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Influence of CBI Requirements on TSCA Implementation

March, 1992

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TSCA Includes Unique Data Collection Provisions

Prior to the enactment of the Toxic Substances Control Act (TSCA), no one knew the number or identity of chemicals in commerce in the United States, much less had information on their production, distribution, use, or health and environmental effects. TSCA has provided an extensive set of tools to collect just such information from industry. If the information does not already exist, industry can be required to develop it. Thus, TSCA is a unique and extremely important source of information that is potentially valuable not only to the United States Environmental Protection Agency (EPA) for its own regulatory efforts, but also to other federal, state, and local programs.

The data collected under TSCA also have the potential to benefit the scientific community as it attempts to better characterize environmental concerns, and industry as it works toward reducing risks of its chemicals. This information further has the potential to benefit workers and the public who risk the consequences of being exposed to any harmful chemical in commerce. Significant amounts of TSCA data are unavailable anywhere else, and TSCA provides the only comprehensive view available of what is known (and not known) about the commercial flow and/or environmental effects of commercial chemicals.

CBI Claims Severely Limit Access to TSCA Data

Under TSCA, large amounts of potentially valuable data have been collected and are being maintained by EPA. However, most of the data are unavailable to scientists, public interest groups, or the general public, because they are being held as confidential business information (CBI). While there are several circumstances under which data submitted by companies are and should be handled as legitimate trade secrets, the majority of the confidentiality claims affecting data submitted under TSCA have not been substantiated, and a significant fraction of these claims would appear not to be supportable under the statute.

Maintaining large volumes of data as CBI not only denies access to interested outside users, it also leads to high costs for the Office of Pollution Prevention and Toxics (OPPT), which administers TSCA, to keep the data secure, impedes the program's ability to develop regulations openly, and makes it difficult for other federal officials to use the data. It also prevents OPPT from sharing the knowledge it gains from reviewing such data about the chemical attributes that give rise to significant health and environmental risks. Thus, TSCA CBI is impeding government regulatory programs, scientific research, industrial chemical stewardship programs, worker and community right-to-know, and industrial accountability. The history of EPA regulation of asbestos provides a telling case in point. The public and interested parties were precluded from meaningful participation in rulemaking, because the documents developed by EPA to support its proposed rule were covered by CBI claims, and could not be made public.

Potential users of TSCA data are not only hindered by the lack of access to the data, but they are also undermined by an inability to ascertain the scope of the data that are being held as confidential. In other words, there is no way for outside users to know whether or not EPA is in possession of data relevant to their interests. Therefore, few groups or individuals, aside from industry, have sought to obtain TSCA data.

The amount of TSCA data claimed and held as CBI is sizeable by any standard, and includes

- more than 90 percent of all premanufacture notices for new chemicals,
- more than 95 percent of all polymer exemption submissions,
- more than 25 percent of all substantial risk notifications (80 percent of those submissions with claims make such claims for chemical identity), and
- more than 20 percent of all reported health and safety studies.

That these TSCA CBI claims are excessive is shown by the following examples:

- Data collected under TSCA's Preliminary Assessment Information Rule have at least 10 times as many confidentiality claims, and probably more than 1,000 times as many claims as Toxics Release Inventory Data submitted to the same EPA program under the Emergency Planning and Community Right-to-Know Act (EPCRA) for a comparable set of information and reporting entities.
- For the limited number of submissions that EPA has had the resources to challenge, submitters have seldom been able to substantiate their claims. (This includes nearly all the substantial risk notices with chemical identity claims.)
- Many of the claims clearly fall outside of what may be claimed as confidential under the explicit provisions of TSCA (*e.g.* health and safety data submitted by industry). Examples include:
    - Claiming chemical identity as CBI on a substantial risk notice, because of concern that toxicity data might be "misinterpreted."
    - Claiming submitter identity and plant site information as confidential, although this information was publicly available, to avoid embarrassment over inadequacies in a medical surveillance program.
- When up-front substantiation requirements for CBI claims were dropped in 1982 for new chemical premanufacture notifications, the percentage of submissions subject to such claims rose noticeably.
- A review of health and safety data on 20 chemicals that have been designated as an international priority for evaluation and control indicated that EPA is holding as confidential five studies submitted under Section 8(d).

Several Strategies are Available to Limit Excessive CBI Claims

EPA cannot prevent firms from making CBI claims under TSCA, and must go through a series of labor-intensive steps to declassify any data that it believes do not meet the statutory criteria for such claims. Therefore, only Congressional action can truly solve the problem of excessive CBI under TSCA. However, there are a limited number of administrative actions that appear to be available to EPA to make TSCA data more available to the public.

Legislative Options

Congressional action will probably be required to modify TSCA before the information reported and generated under the Act can serve more than its current limited regulatory uses to promote environmental health. Congressional options include:

- An explicit legislative restriction on the *classes* of information that may legitimately be claimed as CBI (*e.g.* prohibiting claims on specific data elements, such as the identity of chemicals for which substantial risk notices are submitted, or on combinations of data elements, such as claiming both the chemical and the submitter identity as CBI).

- Following the successful pattern for confidentiality claims demonstrated in Toxics Release Inventory reporting under EPCRA:

  - requiring up-front substantiation of CBI claims;
  - mandating that claims be made by a senior corporate official;
  - providing criminal and civil penalties for false claims of confidentiality;
  - limiting claims to a narrow range of data elements;
  - requiring that each submission covered by a CBI claim be made available to the public with a generic name for each confidential element, so that users of TSCA data can know the exact nature of data covered by CBI claims.

- An explicit authorization for EPA to share data with state governments, and a specification of security requirements that would facilitate data-sharing with other federal agencies.

- Providing EPA with more specific guidance on appropriate provisions for the protection of CBI (*e.g.* specifying sunset periods beyond which additional substantiation of CBI claims would be required).

Options Available to EPA

EPA does have a number of alternatives available to it to limit inappropriate CBI claims, which would supplement Congressional action. These actions by EPA would also have some salutary effects even in the absence of Congressional action. These include:

- Attempting to develop class determinations defining circumstances when EPA considers CBI claims to be invalid;

- Discussing (forcefully) the need to limit inappropriate CBI claims with industrial groups and chief executive officers and seeking voluntary changes from them;

- Continuing the current campaign to challenge those claims least likely to be sustainable, and, in egregious cases of invalid claims, attempting to invoke 18 USC 1001 covering false claims to the government;

- Making internal reforms, under the terms of the consent decrees currently in force, to decrease the administrative burdens of TSCA CBI (several of these are being implemented).

Alternatives to Congressional Action

Should Congress decide not to amend the CBI provisions of TSCA, EPA does have some additional alternatives to discourage inappropriate CBI claims. These might include:

- Publicly disclosing who is making what type of invalid claims (without divulging any confidential specifics);
- Reporting aggregate statistics on information covered by CBI claims, so that at least generic information on risks is available;
- Requiring up-front substantiation for all TSCA CBI claims;
- Instituting procedures that would require re-substantiation of claims after the expiration of fixed periods.
- Imposing fees for CBI claims.

Reform of TSCA CBI procedures, and the elimination of abuses, is possible to some extent without Congressional intervention. However, Congressional action would greatly expedite such reform, and is absolutely necessary to address certain issues, such as access to TSCA CBI by state governments and the ability to prohibit certain classes of CBI claims.

INTRODUCTION

As recently as fifteen years ago, the American public had virtually no information on the risks posed by toxic chemicals in commerce, despite the fact that they were being exposed to these chemicals in the workplace, at home, and outdoors. In addition, neither the scientific nor regulatory communities had the information they needed to assess and control the risks posed by toxic chemicals. Indeed, information was not even available on what, or how many, chemicals were in commercial use in the United States. Adequate information to assess health risks was available for only a tiny portion of the universe of chemicals to which people might be exposed.

The initial proposal for a Toxic Substances Control Act (TSCA) was developed in 1971 in the context of a series of unforseen discoveries of the toxic potential of chemicals in commercial use. These discoveries included the widespread contamination of fish with the heavy metal mercury, and the identification of serious health risks associated with contamination from polychlorinated biphenyls (PCBs), which had been widely used in electrical equipment. As the Administrator of the United States Environmental Protection Agency (EPA), Russell Train, noted:

> Most Americans had no idea, until relatively recently, that they were living so dangerously. They had no idea that when they went to work in the morning, or when they ate their breakfast--that when they did things they had to do to earn a living and keep themselves alive and well--that when they did things as ordinary, as innocent, and as essential as eat, drink, breathe, or touch, they could, in fact, be laying their lives on the line. They had no idea that, without their knowledge or consent, they were engaging in a grim game of chemical roulette whose result they would not know until many years later.[1]

During the six years of debate over the legislation before final enactment of TSCA, there was a seemingly endless stream of revelations regarding chemical risks, including:

- liver cancers in rubber workers induced by vinyl chloride;
- contamination of Lake Superior and water supplies drawn from the lake with asbestos-like fibers;
- plasticizers in blood, coming from plastic blood bags;
- polybrominated biphenyl (PBB) poisoning of cattle in Michigan;
- kepone poisoning of workers and the James River in Virginia;
- "Tris" cancer concerns, from its use as a fire retardant in children's sleepwear; and
- stratospheric ozone depletion induced by chlorofluorocarbons and other chemicals.

TSCA was enacted in 1976, in an effort to identify the risks posed by chemicals in commercial use, and to ensure that the risks of damage to human health and the environment from the manufacture and use of toxic chemicals would be minimized. The Act gives EPA broad authority to collect information on chemicals from manufacturers, processors, and importers throughout the United States. It was hoped that by making this information available to the public, informed choices could be made by everyone concerning chemicals and their use. TSCA also gives EPA the potential to regulate any chemical at any stage in its life cycle from synthesis and development through commercialization, sale, and use, to disposal upon a finding by the Agency that the chemical may pose an unreasonable risk.

One impetus for the passage of TSCA was to fill existing gaps in the federal government's authority to regulate risks from toxic chemicals. Earlier environmental laws had focused on particular environmental media (air, water) or industrial and commercial practices (waste disposal). TSCA

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[1] Legislative History of the Toxic Substances Control Act, U.S. Congress, November 15, 1976, at p. 161.

addressed the entire lifecycle of a chemical substance, from synthesis to disposal. However, rather than simply filling regulatory gaps, most provisions in the Act were intended to *provide information* needed to assess the risks of chemicals, and, thus, to *forestall* problems, rather than correct them. Reporting provisions for existing and reasonably ascertainable information were broadened from the initial Nixon Administration proposal, as were authorities to require testing to develop new data. Finally, premanufacture notification requirements were added to the Act.

The concern was clearly to provide the information needed to support sound regulation of toxic chemicals, but even more so to provide perspectives on chemicals that would move the entire country away from a reactive approach to unknown problems towards a fuller understanding of chemical health and environmental risks. As stated in the Report of the House of Representatives, "the bill provides for the collection of information regarding commercially produced chemicals so that the total exposure to a chemical and its total effect on health and the environment can be monitored and evaluated."[2] TSCA was drafted obtain information needed on the effects of chemicals and on human and environmental exposures to chemicals.

TSCA and Right-to-Know

Public access to the data collected and generated under TSCA was recognized as being essential to the achievement of the statute's ambitious goals. For example, one of the major sponsors of the legislation, Senator Hartke of Indiana stated,

> I think the essential element of this legislation is that it has attempted to provide for the individual--not only who works, but for the rest of American society, the right to know what is in store as far as the toxicity of chemicals is concerned.
>
> The fact of it is that not only do workers not know and the general public not know, but in many cases the manufacturers and distributors and business people do not know.[3]

An example of Congress's recognition of the need for public access to data on toxic chemicals is its decision to add Section 8(d) and related reporting provisions to TSCA. Congress decided to require that health and safety information be reported by all companies under TSCA rules and to make all health and safety studies publicly accessible. Thus, Section 8(d) offered the scientific community (and the public) a window into a pool of unpublished health and safety studies that some have estimated to be larger than the entire published literature. Other provisions of TSCA, such as Sections 8(a) and 8(e), also require the reporting of data on the health and safety effects of chemicals.

Information Gathering and Dissemination Provisions

TSCA contains broad reporting and information provisions. Under Section 8(a), the EPA Administrator can require industry to report almost any existing or reasonably ascertainable (non-financial) information about the chemicals its produces, processes, distributes, uses, or disposes. Such information can be required about specific chemicals and uses or about broad classes of chemicals and

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[2] Legislative History of the Toxic Substances Control Act, U.S. Congress, November 15, 1976, at p. 409.

[3] Legislative History of the Toxic Substances Control Act, U.S. Congress, November 15, 1976, at p. 218.

uses. In fact, such reporting requirements can be constructed to encompass any logical class of chemicals, uses, or other groupings, except the group "all new chemicals."

Under Section 8(b), EPA was required to exercise its reporting authorities to obtain an inventory of all existing chemicals in commerce. EPA acted in 1977, and supplemented the inventory with reporting on the site and amount of manufacture (or import). (The inventory is regularly updated and the production information has been updated twice since.)

In addition to Section 8(d) authority, mandating that EPA collect unpublished health and safety studies from industry, two other important authorities in Section 8 allow EPA to require reporting of health and safety data. First, under Section 8(e), industry is required to report to EPA any additional data that "reasonably supports the conclusion that a substance presents a substantial risk of injury to health or the environment." Under Section 8(c), EPA is to establish rules for industry to maintain and report records of adverse reactions to health or the environment of its chemicals and of allegations of such adverse reactions.

Finally, TSCA grants EPA authority to require industry to generate any missing data that are needed on new chemicals (under Section 5) and existing chemicals (under Section 4 test rules). For new chemicals, if EPA determines that a chemical *may* pose an unreasonable risk to human health or the environment, it can require any studies necessary to make a risk determination. Under Section 4, EPA can develop rules that require any testing that may be needed to develop information on chemicals already in commerce.

TSCA's information-gathering tools cover the entire universe of old and new chemicals, and the entire range of uses of any chemical, unless the chemical is already regulated as a pesticide, food or food additive, or drug. These tools cover all stages in the commercial flow of such chemicals, from production, processing, distribution, and use, to treatment and disposal. They embrace information on production, use, exposure, and environmental release, as well as health and environmental effects. In fact, TSCA covers virtually any type of information about chemicals in commerce and their effects.

By collecting information under TSCA, EPA can better set priorities for its regulatory and enforcement activities under all its statutes. By making such information publicly available, as required by the Act, EPA provides producers and users (both commercial and private) with the ability to make better decisions regarding chemicals, and requires producers to be publicly accountable for their actions. As has been illustrated by the impact of the Emergency Planning and Community Right to Know Act of 1986 (EPCRA) on corporate practices, such publicly available information may be a far more powerful influence on environmental quality than direct EPA regulation.

Unique Aspects of TSCA Data

TSCA is not the only, nor even the major source of information on toxic substances. Thousands of trade publications and the huge body of scientific literature contain much information about toxic substances. However, there are two aspects of the TSCA data are both important and unique.

First, significant amounts of *TSCA data are unavailable anywhere else.* Under TSCA, EPA can require companies to submit information on their production, distribution, uses, and disposal of chemicals, as well as information relating to their possible health or environmental effects. An important portion of the information that companies have on their chemicals has not been published. Therefore, TSCA is receiving data not available anywhere outside of the companies submitting them. In addition, if such data do not exist, but EPA finds that the chemical may pose an unreasonable risk or that the chemical has large production and has significant or substantial exposure, then the Agency may

require companies to generate such data. Thus, TSCA information-gathering authorities can and do fill key gaps in information about chemicals. For example, for hundreds of chemicals designated as high priority for testing by the Interagency Testing Committee, TSCA has been used by EPA first to obtain all unpublished health and safety data and then to have industry conduct tests to fill key gaps in these data.

Second, *TSCA provides the only comprehensive view available of what is known (and not known) about the commercial flow and/or environmental effects of commercial chemicals.* For example, nowhere else is there a complete overview of what chemicals are being produced, in what quantities, and where. Nowhere else are there complete compilations of the existing health and safety data on important environmental chemicals, including large databases containing unpublished data. Nowhere else is there a complete overview of what new chemicals have been developed and introduced into commerce in the U.S. And, nowhere else is there a complete overview of the commercial uses of chemicals that pose high risks, such as lead and asbestos.

As a result of these information-gathering provisions, OPPT has an absolutely unique overview on chemicals. For example, it has no equal in knowledge of the chemical features that give rise to health and environmental concerns from having collected and reviewed thousands of published and unpublished health and safety studies on chemicals with similar structural features. This is information of value not only to EPA in its oversight of new chemical development, but also to research scientists in their efforts to understand mechanisms of toxicity and drug action and to industry in its efforts to design and develop safer chemicals.

Confidential Business Information

Manufacturers, processors, and users of chemicals protect many trade secrets from disclosure to one another. Such trade secrets may involve for example: the nature of their research programs and marketing plans, the specific formulation of their products, the details of their process steps, or the economics of their operations. Disclosure of such trade secrets may allow domestic and foreign competitors to avoid the time and expense to independently develop such information, and, thus, can result in such competitors' obtaining an unfair competitive advantage over the company whose secrets have been disclosed.

Recognizing the legitimate concerns of companies over unnecessary disclosure of such trade secrets, TSCA contains provisions limiting disclosure of confidential business information. However, given TSCA's overall thrust of improving the public's access to information, such provisions place narrow limitations on what information is to be publicly withheld. In particular, Section 14(a) of TSCA mirrors the provisions of the Freedom of Information Act (FOIA), which allow "any information" submitted or obtained under TSCA to be claimed as confidential, but limit what may be held confidential to data needed to protect "trade secrets or financial information."

Moreover, under Section 14(b), the range of submitted data from health and safety studies that can be protected as CBI is far more limited. Even information that would normally be protected from disclosure under FOIA may be disclosed under this provision of TSCA. Only data that disclose "processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, ... any data which discloses the portion of the mixture comprised by any of the chemical substances in the mixture" is prohibited from release.

That Congress did not intend for these limitations to restrict information necessary to protect public health and safety is demonstrated by the fact that Section 14(a) also contains a provision for disclosure of information that would otherwise be entitled to protection as TSCA CBI under several sets of

conditions. CBI may be disclosed if doing so is necessary to prevent unreasonable risk. Officers and employees of the United States and contractors may review confidential information if it is necessary to perform their duties in protecting health and the environment or for specific law enforcement purposes (for example, if worker exposures are possible, officials of the Occupational Safety and Health Administration (OSHA) are entitled to review TSCA CBI, in order to carry out their duties under the Occupational Safety and Health Act). Disclosure is also allowed when relevant to a proceeding under TSCA, although all efforts must be made to preserve the confidentiality of substantiated CBI to the extent practicable. In addition, Congressional committees may review confidential information obtained under TSCA upon written request by the committee seeking information.

Purpose and Scope of This Report

This report examines whether the CBI provisions of TSCA, either as explicitly mandated by the statute or as put into practice by EPA, have had a deleterious effect on the implementation and impact of the law. It considers procedures for claiming CBI and the number and nature of CBI claims that have been made regarding information submitted to EPA under TSCA. Subsequent sections examine the validity of the claims that have been made, the impacts of CBI claims on the utility of TSCA information for EPA and the public, and the advantages and disadvantages associated with some proposed alterations of TSCA CBI procedures.

This assessment of TSCA CBI is based upon a review of the legislative history and other legal and historical documents to identify the statutory, regulatory, and case-law constraints on confidential claims under TSCA. Statistical analyses of TSCA data contained in EPA databases were performed to quantify and document the scope of CBI claims through FY 1990. As a final component of the assessment, interviews were conducted with EPA staff and outside parties interested in data submitted under TSCA, to ascertain the extent of the problem caused by claims of confidentiality. These interviews also sought opinions on the utility of various potential modifications of EPA confidentiality procedures.

CLAIMING CONFIDENTIAL BUSINESS INFORMATION

Claiming information as confidential is a simple procedure under TSCA. Information submitted is claimed as confidential business information by marking the specific information with a label such as "confidential," "proprietary," or "trade secret." Under some sections of TSCA, EPA has provided for information to be claimed as confidential by simply checking a box on the appropriate form (*e.g.* new chemicals under Section 5). Under other sections, written substantiation of the confidentiality of the claim is required. For example, claims associated with Inventory reporting require detailed answers for a list of questions specified under 40 CFR 710.7(a) and (b).

For several types of submissions (including Premanufacture Notices, health and safety studies, and records of significant adverse reactions), the regulations issued under TSCA specify that two copies of the information are submitted. The first copy must contain all the information required for reporting. This copy of the submission is used internally by EPA. The second copy (also known as the "sanitized version") must contain only information not claimed as CBI and is placed in an open file available to the public. These sanitized copies of submissions frequently do not indicate either the nature or amount of CBI information from the original submission that has been omitted. If the submitter fails to supply a sanitized copy, EPA notifies the submitter who then has either 15 or 30 working days (depending on the applicable section of TSCA) to submit the second copy. If EPA does not receive this second copy, the confidentiality claim is waived and the information is placed in the open file.

There are no penalties under TSCA for false claims of confidentiality. In stark contrast, the penalties applicable to EPA staff or contractors who reveal CBI (even if the CBI claim is frivolous) can be substantial.

Because the information submitted to EPA under various sections of TSCA differs, the nature of the information likely to be claimed as CBI, and the presumptions regarding CBI, differ somewhat in the programs corresponding to these sections of the Act. The section below analyzes CBI claims that are clearly important from a health and safety point of view.

THE LARGE AND INCREASING VOLUME OF CBI CLAIMS FROM 1977 to 1990

Since FY 1982, there has been a massive increase in the number of CBI claims affecting information submitted to the EPA under TSCA. In part, this reflects a nearly exponential increase in the number of documents submitted to EPA under the statute. However, the increase in the number of CBI claims also reflects changes in CBI claim patterns from the early years of TSCA to more recent times. This increase in CBI claims affects many types of submissions, including Premanufacture Notices submitted pursuant to Section 5, substantial risk notices submitted pursuant to Section 8(e), health and safety studies submitted under Section 8(d), and so forth.

Reports from databases maintained by EPA's Office of Pollution Prevention and Toxics (OPPT), which administers TSCA, were used to track the number and nature of CBI claims over the last 14 years. These non-CBI reports presented counts of the numbers of each type of document submitted in any fiscal year, the numbers of each containing *any* CBI claims, and the numbers containing CBI claims for each of several key data fields (*e.g.* chemical identity, submitter identity, use, etc.). Most of the relevant data are contained in the Document and Personnel Security System (DAPSS), although data on PMN submissions were obtained from the PENTA database. Data from FY 1977 through FY 1990 were analyzed.[4] Submissions for each class of documents are described below.

It is important to note that increases in the proportion of CBI claims for any submission type suggest an increase in the number of unnecessary, and therefore invalid, claims. There is no reason to expect, *a priori*, that submitters' need to protect truly confidential information has increased over the past 14 years; one would expect the proportion of data subject to legitimate confidentiality concerns to fluctuate somewhat, but not to markedly increase or decrease. If the proportion of submissions with CBI *claims* increases, the most probable explanation is that information of a type and level of sensitivity that was not previously claimed as CBI is being so claimed.

The New Chemicals Program (Section 5)

Section 5(a)(1) of TSCA establishes the Pre-Manufacture Notification (PMN) program which requires manufacturers or importers to provide 90-day notification prior to introducing a new chemical into commerce. A "new" chemical is defined as a commercial chemical not listed on the TSCA Inventory. Manufacturers are required to submit available risk-related data including results of relevant health and safety studies, projected production or import volumes, exposure estimates, and intended methods of disposal. (See Appendix A for a copy of the PMN form.) Based on the information provided in the PMN, EPA must assess the risks to ascertain if the chemical may or will pose an unreasonable risk to human health or the environment.

When EPA receives the PMN, a number is assigned and a notice is sent to the submitter identifying the PMN number and the date on which the review period begins (40 CFR 720.65). The standard review period is 90 days. The procedures for claiming any reported information as confidential are consistent with the general procedure. Claims of confidentiality for the chemical identity apply only to

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[4] OPPT also has complete data for FY 1991, but these have not been included in our analysis. In 1991, EPA's Confidential Systems Section phased out the use of DAPSS, replacing it with the Confidential Business Information Tracking System (CBITS). Because data for 1991 are contained in two separate systems, and the degree of overlap between the systems is unclear, it would be impossible to analyze these data without individually examining each record for FY 1991 in each system.

the period prior to commencement of manufacture or import for commercial purposes (40 CFR 720.85(a)).

If the chemical identity of the new chemical substance is claimed as confidential, the submitter must provide a generic name at the time of the claim. Once a generic name is accepted by EPA and the submitter, it is published in the Federal Register.

Exemptions to the PMN process are made for polymers (40 CFR 723.250) chemicals developed solely for use in research and development (40 CFR 720.36), chemicals distributed solely for test market purposes (40 CFR 720.38), and chemicals produced in low volumes (less than 1,000 kilograms per year (40 CFR 723.50). A company may also be exempt from reporting if the new chemical is identical to one listed with EPA under a generic chemical name. EPA will reveal that the chemical is already on the inventory list once the company establishes that it has a *bona fide* intent to manufacture the chemical. (Additional information on the new chemicals program is included in Appendix B.)

A company must send a Notice of Commencement of Manufacture to EPA no later than 30 days after it begins manufacturing or importing the chemical substance for commercial purposes. This notice reports such information as the chemical identity, pre-manufacture notice number, and the date when manufacture or import started. If the submitter would like to maintain the chemical identity as confidential, he or she must reassert and substantiate the claim, or else the chemical identity is placed on the public inventory without notice (40 CFR 720.102(c)). A submitter may not claim the chemical identity confidential after manufacture or import unless a claim of confidentiality was made prior to manufacture or import (40 CFR 720.85 (b)(1)). Although the statute is not explicit on other claims, it is EPA practice to maintain any other information claimed in the PMN as CBI after the Notice of Commencement has been received by EPA, without requiring further substantiation.

PMN Submissions

As can be seen from Figure 1, the number of PMN submissions to OPPT has increased substantially over the past decade, from 35 submissions in 1979 (the first year in which any were reported) to a maximum of 2,645 in 1988 (the drop in FY 1989 to 1150 submissions presumably reflects EPA's imposition of a processing fee, with submissions that might have been expected in 1989 being made in 1988 to avoid the fee).

In FY 1983, the absolute number of PMN submissions nearly doubled from the preceding year (from 709 to 1,342). At this time, there also appears to be a significant increase in the *proportion* of PMN submissions affected by CBI claims, relative to the preceding three years (from 70% to 79%). Definitive data are not available for overall CBI claim rates, but claims on chemical identity increase from 70% to 79%, and this higher claim rate is maintained in subsequent years. Similar, but smaller, increases in CBI claim rates are seen for use, process, plant site, and chemical property data. One explanation for these changes can be found in the procedures specified by EPA for asserting CBI claims. Prior to FY 1983, EPA had an "interim" policy that CBI claims be substantiated at the time they were asserted ("up-front" substantiation). This policy was discontinued in a notice published toward the end of FY 1982 (47 FR 28969, 7/2/82) (confirmed in the Final Rule published during FY 1983; 48 FR 21722, 5/13/83).

Polymer, Low Volume, and Test Market Exemption Submissions

EPA has separately tracked Polymer and Low Volume Exemption Submissions since FY 1985. These chemicals are presumed to be associated with a lower probability of posing substantial risks, in that polymers tend to be chemically non-reactive, while chemicals produced in low volumes should have

uses. In fact, such reporting requirements can be constructed to encompass any logical class of chemicals, uses, or other groupings, except the group "all new chemicals."

Under Section 8(b), EPA was required to exercise its reporting authorities to obtain an inventory of all existing chemicals in commerce. EPA acted in 1977, and supplemented the inventory with reporting on the site and amount of manufacture (or import). (The inventory is regularly updated and the production information has been updated twice since.)

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Finally, TSCA grants EPA authority to require industry to generate any missing data that are needed on new chemicals (under Section 5) and existing chemicals (under Section 4 test rules). For new chemicals, if EPA determines that a chemical *may* pose an unreasonable risk to human health or the environment, it can require any studies necessary to make a risk determination. Under Section 4, EPA can develop rules that require any testing that may be needed to develop information on chemicals already in commerce.

TSCA's information-gathering tools cover the entire universe of old and new chemicals, and the entire range of uses of any chemical, unless the chemical is already regulated as a pesticide, food or food additive, or drug. These tools cover all stages in the commercial flow of such chemicals, from production, processing, distribution, and use, to treatment and disposal. They embrace information on production, use, exposure, and environmental release, as well as health and environmental effects. In fact, TSCA covers virtually any type of information about chemicals in commerce and their effects.

By collecting information under TSCA, EPA can better set priorities for its regulatory and enforcement activities under all its statutes. By making such information publicly available, as required by the Act, EPA provides producers and users (both commercial and private) with the ability to make better decisions regarding chemicals, and requires producers to be publicly accountable for their actions. As has been illustrated by the impact of the Emergency Planning and Community Right to Know Act of 1986 (EPCRA) on corporate practices, such publicly available information may be a far more powerful influence on environmental quality than direct EPA regulation.

Unique Aspects of TSCA Data

TSCA is not the only, nor even the major source of information on toxic substances. Thousands of trade publications and the huge body of scientific literature contain much information about toxic substances. However, there are two aspects of the TSCA data are both important and unique.

First, significant amounts of *TSCA data are unavailable anywhere else.* Under TSCA, EPA can require companies to submit information on their production, distribution, uses, and disposal of chemicals, as well as information relating to their possible health or environmental effects. An important portion of the information that companies have on their chemicals has not been published. Therefore, TSCA is receiving data not available anywhere outside of the companies submitting them. In addition, if such data do not exist, but EPA finds that the chemical may pose an unreasonable risk or that the chemical has large production and has significant or substantial exposure, then the Agency may

require companies to generate such data. Thus, TSCA information-gathering authorities can and do fill key gaps in information about chemicals. For example, for hundreds of chemicals designated as high priority for testing by the Interagency Testing Committee, TSCA has been used by EPA first to obtain all unpublished health and safety data and then to have industry conduct tests to fill key gaps in these data.

Second, *TSCA provides the only comprehensive view available of what is known (and not known) about the commercial flow and/or environmental effects of commercial chemicals.* For example, nowhere else is there a complete overview of what chemicals are being produced, in what quantities, and where. Nowhere else are there complete compilations of the existing health and safety data on important environmental chemicals, including large databases containing unpublished data. Nowhere else is there a complete overview of what new chemicals have been developed and introduced into commerce in the U.S. And, nowhere else is there a complete overview of the commercial uses of chemicals that pose high risks, such as lead and asbestos.

As a result of these information-gathering provisions, OPPT has an absolutely unique overview on chemicals. For example, it has no equal in knowledge of the chemical features that give rise to health and environmental concerns from having collected and reviewed thousands of published and unpublished health and safety studies on chemicals with similar structural features. This is information of value not only to EPA in its oversight of new chemical development, but also to research scientists in their efforts to understand mechanisms of toxicity and drug action and to industry in its efforts to design and develop safer chemicals.

Confidential Business Information

Manufacturers, processors, and users of chemicals protect many trade secrets from disclosure to one another. Such trade secrets may involve for example: the nature of their research programs and marketing plans, the specific formulation of their products, the details of their process steps, or the economics of their operations. Disclosure of such trade secrets may allow domestic and foreign competitors to avoid the time and expense to independently develop such information, and, thus, can result in such competitors' obtaining an unfair competitive advantage over the company whose secrets have been disclosed.

Recognizing the legitimate concerns of companies over unnecessary disclosure of such trade secrets, TSCA contains provisions limiting disclosure of confidential business information. However, given TSCA's overall thrust of improving the public's access to information, such provisions place narrow limitations on what information is to be publicly withheld. In particular, Section 14(a) of TSCA mirrors the provisions of the Freedom of Information Act (FOIA), which allow "any information" submitted or obtained under TSCA to be claimed as confidential, but limit what may be held confidential to data needed to protect "trade secrets or financial information."

Moreover, under Section 14(b), the range of submitted data from health and safety studies that can be protected as CBI is far more limited. Even information that would normally be protected from disclosure under FOIA may be disclosed under this provision of TSCA. Only data that disclose "processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, ... any data which discloses the portion of the mixture comprised by any of the chemical substances in the mixture" is prohibited from release.

That Congress did not intend for these limitations to restrict information necessary to protect public health and safety is demonstrated by the fact that Section 14(a) also contains a provision for disclosure of information that would otherwise be entitled to protection as TSCA CBI under several sets of

conditions. CBI may be disclosed if doing so is necessary to prevent unreasonable risk. Officers and employees of the United States and contractors may review confidential information if it is necessary to perform their duties in protecting health and the environment or for specific law enforcement purposes (for example, if worker exposures are possible, officials of the Occupational Safety and Health Administration (OSHA) are entitled to review TSCA CBI, in order to carry out their duties under the Occupational Safety and Health Act). Disclosure is also allowed when relevant to a proceeding under TSCA, although all efforts must be made to preserve the confidentiality of substantiated CBI to the extent practicable. In addition, Congressional committees may review confidential information obtained under TSCA upon written request by the committee seeking information.

Purpose and Scope of This Report

This report examines whether the CBI provisions of TSCA, either as explicitly mandated by the statute or as put into practice by EPA, have had a deleterious effect on the implementation and impact of the law. It considers procedures for claiming CBI and the number and nature of CBI claims that have been made regarding information submitted to EPA under TSCA. Subsequent sections examine the validity of the claims that have been made, the impacts of CBI claims on the utility of TSCA information for EPA and the public, and the advantages and disadvantages associated with some proposed alterations of TSCA CBI procedures.

This assessment of TSCA CBI is based upon a review of the legislative history and other legal and historical documents to identify the statutory, regulatory, and case-law constraints on confidential claims under TSCA. Statistical analyses of TSCA data contained in EPA databases were performed to quantify and document the scope of CBI claims through FY 1990. As a final component of the assessment, interviews were conducted with EPA staff and outside parties interested in data submitted under TSCA, to ascertain the extent of the problem caused by claims of confidentiality. These interviews also sought opinions on the utility of various potential modifications of EPA confidentiality procedures.

CLAIMING CONFIDENTIAL BUSINESS INFORMATION

Claiming information as confidential is a simple procedure under TSCA. Information submitted is claimed as confidential business information by marking the specific information with a label such as "confidential," "proprietary," or "trade secret." Under some sections of TSCA, EPA has provided for information to be claimed as confidential by simply checking a box on the appropriate form (*e.g.* new chemicals under Section 5). Under other sections, written substantiation of the confidentiality of the claim is required. For example, claims associated with Inventory reporting require detailed answers for a list of questions specified under 40 CFR 710.7(a) and (b).

For several types of submissions (including Premanufacture Notices, health and safety studies, and records of significant adverse reactions), the regulations issued under TSCA specify that two copies of the information are submitted. The first copy must contain all the information required for reporting. This copy of the submission is used internally by EPA. The second copy (also known as the "sanitized version") must contain only information not claimed as CBI and is placed in an open file available to the public. These sanitized copies of submissions frequently do not indicate either the nature or amount of CBI information from the original submission that has been omitted. If the submitter fails to supply a sanitized copy, EPA notifies the submitter who then has either 15 or 30 working days (depending on the applicable section of TSCA) to submit the second copy. If EPA does not receive this second copy, the confidentiality claim is waived and the information is placed in the open file.

There are no penalties under TSCA for false claims of confidentiality. In stark contrast, the penalties applicable to EPA staff or contractors who reveal CBI (even if the CBI claim is frivolous) can be substantial.

Because the information submitted to EPA under various sections of TSCA differs, the nature of the information likely to be claimed as CBI, and the presumptions regarding CBI, differ somewhat in the programs corresponding to these sections of the Act. The section below analyzes CBI claims that are clearly important from a health and safety point of view.

THE LARGE AND INCREASING VOLUME OF CBI CLAIMS FROM 1977 to 1990

Since FY 1982, there has been a massive increase in the number of CBI claims affecting information submitted to the EPA under TSCA. In part, this reflects a nearly exponential increase in the number of documents submitted to EPA under the statute. However, the increase in the number of CBI claims also reflects changes in CBI claim patterns from the early years of TSCA to more recent times. This increase in CBI claims affects many types of submissions, including Premanufacture Notices submitted pursuant to Section 5, substantial risk notices submitted pursuant to Section 8(e), health and safety studies submitted under Section 8(d), and so forth.

Reports from databases maintained by EPA's Office of Pollution Prevention and Toxics (OPPT), which administers TSCA, were used to track the number and nature of CBI claims over the last 14 years. These non-CBI reports presented counts of the numbers of each type of document submitted in any fiscal year, the numbers of each containing *any* CBI claims, and the numbers containing CBI claims for each of several key data fields (*e.g.* chemical identity, submitter identity, use, etc.). Most of the relevant data are contained in the Document and Personnel Security System (DAPSS), although data on PMN submissions were obtained from the PENTA database. Data from FY 1977 through FY 1990 were analyzed.[4] Submissions for each class of documents are described below.

It is important to note that increases in the proportion of CBI claims for any submission type suggest an increase in the number of unnecessary, and therefore invalid, claims. There is no reason to expect, *a priori*, that submitters' need to protect truly confidential information has increased over the past 14 years; one would expect the proportion of data subject to legitimate confidentiality concerns to fluctuate somewhat, but not to markedly increase or decrease. If the proportion of submissions with CBI *claims* increases, the most probable explanation is that information of a type and level of sensitivity that was not previously claimed as CBI is being so claimed.

The New Chemicals Program (Section 5)

Section 5(a)(1) of TSCA establishes the Pre-Manufacture Notification (PMN) program which requires manufacturers or importers to provide 90-day notification prior to introducing a new chemical into commerce. A "new" chemical is defined as a commercial chemical not listed on the TSCA Inventory. Manufacturers are required to submit available risk-related data including results of relevant health and safety studies, projected production or import volumes, exposure estimates, and intended methods of disposal. (See Appendix A for a copy of the PMN form.) Based on the information provided in the PMN, EPA must assess the risks to ascertain if the chemical may or will pose an unreasonable risk to human health or the environment.

When EPA receives the PMN, a number is assigned and a notice is sent to the submitter identifying the PMN number and the date on which the review period begins (40 CFR 720.65). The standard review period is 90 days. The procedures for claiming any reported information as confidential are consistent with the general procedure. Claims of confidentiality for the chemical identity apply only to

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[4] OPPT also has complete data for FY 1991, but these have not been included in our analysis. In 1991, EPA's Confidential Systems Section phased out the use of DAPSS, replacing it with the Confidential Business Information Tracking System (CBITS). Because data for 1991 are contained in two separate systems, and the degree of overlap between the systems is unclear, it would be impossible to analyze these data without individually examining each record for FY 1991 in each system.

the period prior to commencement of manufacture or import for commercial purposes (40 CFR 720.85(a)).

If the chemical identity of the new chemical substance is claimed as confidential, the submitter must provide a generic name at the time of the claim. Once a generic name is accepted by EPA and the submitter, it is published in the Federal Register.

Exemptions to the PMN process are made for polymers (40 CFR 723.250) chemicals developed solely for use in research and development (40 CFR 720.36), chemicals distributed solely for test market purposes (40 CFR 720.38), and chemicals produced in low volumes (less than 1,000 kilograms per year (40 CFR 723.50). A company may also be exempt from reporting if the new chemical is identical to one listed with EPA under a generic chemical name. EPA will reveal that the chemical is already on the inventory list once the company establishes that it has a *bona fide* intent to manufacture the chemical. (Additional information on the new chemicals program is included in Appendix B.)

A company must send a Notice of Commencement of Manufacture to EPA no later than 30 days after it begins manufacturing or importing the chemical substance for commercial purposes. This notice reports such information as the chemical identity, pre-manufacture notice number, and the date when manufacture or import started. If the submitter would like to maintain the chemical identity as confidential, he or she must reassert and substantiate the claim, or else the chemical identity is placed on the public inventory without notice (40 CFR 720.102(c)). A submitter may not claim the chemical identity confidential after manufacture or import unless a claim of confidentiality was made prior to manufacture or import (40 CFR 720.85 (b)(1)). Although the statute is not explicit on other claims, it is EPA practice to maintain any other information claimed in the PMN as CBI after the Notice of Commencement has been received by EPA, without requiring further substantiation.

PMN Submissions

As can be seen from Figure 1, the number of PMN submissions to OPPT has increased substantially over the past decade, from 35 submissions in 1979 (the first year in which any were reported) to a maximum of 2,645 in 1988 (the drop in FY 1989 to 1150 submissions presumably reflects EPA's imposition of a processing fee, with submissions that might have been expected in 1989 being made in 1988 to avoid the fee).

In FY 1983, the absolute number of PMN submissions nearly doubled from the preceding year (from 709 to 1,342). At this time, there also appears to be a significant increase in the *proportion* of PMN submissions affected by CBI claims, relative to the preceding three years (from 70% to 79%). Definitive data are not available for overall CBI claim rates, but claims on chemical identity increase from 70% to 79%, and this higher claim rate is maintained in subsequent years. Similar, but smaller, increases in CBI claim rates are seen for use, process, plant site, and chemical property data. One explanation for these changes can be found in the procedures specified by EPA for asserting CBI claims. Prior to FY 1983, EPA had an "interim" policy that CBI claims be substantiated at the time they were asserted ("up-front" substantiation). This policy was discontinued in a notice published toward the end of FY 1982 (47 FR 28969, 7/2/82) (confirmed in the Final Rule published during FY 1983; 48 FR 21722, 5/13/83).

Polymer, Low Volume, and Test Market Exemption Submissions

EPA has separately tracked Polymer and Low Volume Exemption Submissions since FY 1985. These chemicals are presumed to be associated with a lower probability of posing substantial risks, in that polymers tend to be chemically non-reactive, while chemicals produced in low volumes should have

correspondingly low exposure potential. As illustrated in Figure 3 (Polymer) and Figure 4 (Low Volume), a substantial number of each type of submission has been received, an average of 260 polymer submissions per year (maximum of 360), and an average of 297 Low Volume submissions per year (maximum of 592). While the rate of Polymer submissions is relatively steady, Low Volume exemption applications increased significantly in FY 1990.

As is also evident from Figures 3 and 4, both classes of submission are almost uniformly covered by CBI claims (95 percent or more of Polymer submissions and between 78 percent and 93 percent of Low Volume submissions). For Polymer submissions, CBI claims relate mostly to chemical identity, with roughly half the submissions claiming submitter identity, and half claiming use information, with lower claim proportions for other key data fields. For Low Volume submissions, approximately three quarters of the submissions claim chemical identity as CBI, with claim rates for other key data elements similar to those for Polymer submissions.

Test Market Exemption submissions do not follow the general pattern of a consistent increase in submissions, but rather show a peak in 1983 (169 submitted) and 1984 (168 submitted); the proportion covered by CBI claims is consistent, and high (greater than 90 percent for all years except FY 1985). None of the individual key data elements alone accounts for this high rate. Chemical identity, submitter identity, and use information are claimed on more than 50 percent of the forms for most reporting years.

Bona Fide Submissions

If, on the basis of a generic chemical name on the TSCA inventory, a submitter who would otherwise have to submit a PMN believes that a chemical it intends to manufacture or import may already be in commercial use, it submits to the EPA a declaration that it has a *bona fide* intent to manufacture or import the chemical. On the basis of this submission, the EPA is able to divulge whether or not the subject chemical is or is not on the inventory.[5]

A moderate number of *bona fide* submissions were received by EPA between FY 1979 and FY 1982 (Figure 5). There was a substantial increase in these submissions in FY 1983 and FY 1984, with some decline thereafter. Nearly all of the *bona fide* submissions are affected by CBI claims, although the proportion so affected has declined since 1985.

Substantial Risk Information; Health and Safety Data (Section 8)

As noted above, Section 8 of TSCA provides EPA with a variety of mechanisms to obtain information on the potential health and environmental risks associated with chemicals once they have entered into commercial use. Beyond the basic commercial information contained in the chemical inventory mandated by Section 8(b), EPA is provided with mandatory reporting of information indicating substantial risks (Section 8(e)), the ability to require submission of any health and safety data (Section 8(d)) or reports of significant adverse reactions (Section 8(c)) that must be maintained by a manufacturer or importer, and the ability to promulgate additional rules that require recordkeeping

[5] This represents an interesting approach to the protection of business-related information, in that knowledge regarding the identity of a chemical that has been claimed as confidential by the current manufacturer or importer is made available *only* to that company's direct competitors (those proposing to manufacture or import the same chemical). All that is reported is the fact that the chemical is in commerce.

and/or reporting by manufacturers and importers (Section 8(a)). Additional information on the provisions of Section 8 are provided in Appendix C.

8(e) and FYI Submissions

Under Section 8(e) of TSCA, manufacturers, distributors, and processors must notify EPA immediately if they obtain information indicating that a chemical presents "a substantial risk of injury to health or the environment." As discussed in a subsequent section, legal analysts at EPA have taken the position that "health and safety data", as specified in the statute, are *not* limited to the health and safety studies covered by Section 8(d). Data reported under Section 8(e) also meet the definition of a health and safety study under the Act, and are therefore subject to the limited CBI protection of Section 14(b). However, to date EPA has dealt with CBI claims on such submissions according to the general procedure, following Section 14(a).

In addition to the 8(e) notices specified in the Act, EPA receives a significant number of similar submissions, termed "FYI" (For Your Information) notices. These notices represent cases in which the submitter asserts that the information reported is not subject to mandatory reporting under Section 8(e), but is reported voluntarily. It could be argued that the information reported in FYI notices would more properly be incorporated into 8(e) notices; this is a matter of judgement that EPA has left to the discretion of submitters. From the point of view of CBI claims, they can be treated similarly.

A key fact to remember in reviewing CBI claims for 8(e) and FYI notices is that unlike notices received under the new chemicals program, for which one can not *a priori* assume that a chemical poses any risk at all, 8(e) notices *by definition* deal with substantial risks, and FYI notices with risks of sufficient magnitude that the submitter believes EPA should be apprised of them.

The number of 8(e) notices received by EPA to date has been far lower than the number of notices under the new chemicals program, with fewer than 150 such submissions in any year prior to FY 1990. Relatively few such submissions were received by EPA between 1977 and 1982 (an average of 15 per year), with the number of submissions per year jumping up to a higher level for 1983-1986 (average of 126 per year), decreasing from 1987-1989 (64 per year), and increasing considerably in 1990 (256 submissions) (Figure 6).

However, the low numbers of 8(e) submissions received to date may not accurately reflect a lack of information indicating substantial risks associated with chemicals in commerce. EPA has taken the position that many submissions that *should have* been made under Section 8(e) were not, in fact, made. The Agency recently instituted a penalty cap program to encourage submissions of these "missing" 8(e) notices. The announcement of this program may account for the substantial increase in 8(e) submissions seen in FY 1990; EPA expects a significantly increased number of 8(e) submissions in the near future; OPPT discussions with industry have indicated that as many as several thousand may be received.

One would expect, in view of the explicit limitations on CBI claims for health and safety data contained in Section 14(b), that the proportion of 8(e) notices affected by CBI claims would be far less than that for new chemical submissions. The proportion of 8(e) submissions containing *any* CBI claims is, in fact, much lower than that seen in the new chemicals program, with the proportion of CBI claims decreasing in 1983, when the absolute number of submissions first increases substantially. Of the submissions since 1983, fewer than 50 percent contain any CBI, in contrast to the greater than 90 percent claim rate for PMNs. A 50 percent incidence of CBI claims, however, is still substantial, particularly in view of the fact that these submissions deal with chemicals that have been judged to potentially present a substantial risk of harm to human health or the environment, and the fact that the burden of substantiation for CBI claims on such submissions was intended by Congress to be greater

than for other submissions. As Figure 7 illustrates, a substantial number of the CBI claims associated with 8(e) notices concern chemical identity; moreover, the assertion of CBI claims regarding chemical identity in 8(e) notices appears to increase from FY 1985 onward. As is discussed in greater detail below, the inability of potentially exposed persons to determine the identity of chemicals that pose substantial risks severely restricts their ability to take actions to protect themselves from those risks. As is also discussed below, EPA's recent program challenging CBI assertions in 8(e) notices indicates that a substantial fraction of these CBI claims may be invalid under the statute.

FYI submissions in significant numbers are first recorded in 1987, and have remained relatively constant at 150 to 200 per year (Figure 8). Until 1990, the number of FYIs exceeded that of 8(e)s by a ratio of five to two; in 1990, more 8(e)s than FYIs were submitted (256 vs. 158). EPA staff have speculated that submitters have filed FYIs in preference to 8(e)s in order to avoid the stigma associated with a finding of "substantial risk," as well as to avoid the procedural requirements of 8(e) notification.

A relatively low proportion of FYIs contain CBI claims (9 to 19 percent), but there has been a steady increase in claims from 1987 through 1990, and many of these claims concern chemical identity. These increases are of particular interest because these submissions are ostensibly voluntary. However, the proportion of FYI submissions in which chemical identity is claimed as CBI has remained consistently lower than the corresponding figure for 8(e) submissions (10 to 20 percent vs. 30 to 45 percent over the same four years). Again, this may reflect the perceived stigma associated with an 8(e) submission.

Significant Adverse Reactions (Section 8(c))

EPA defines significant adverse reactions as those "that may indicate a substantial impairment of normal activities, or long-lasting or irreversible damage to health or the environment." (40 CFR 717.3(i)). Section 8(c) of TSCA requires manufacturers, processors, and distributors of chemicals or mixtures to keep records of significant adverse reactions to health or the environment alleged to have been caused by their chemicals. Firms must make records of allegations available to EPA upon request. Any person who is submitting copies of these records is allowed to assert a confidentiality claim, by submitting both complete and non-confidential ("sanitized") versions of the submission (40 CFR 717.19).

Almost all (21 of 26) of the 8(c) submissions requested by EPA were received in 1988. Again, one would expect a low incidence of CBI claims, because these reports satisfy the definition of a health and safety study, and would be covered by the limited CBI provisions of Section 14(b). Roughly half of these submissions to EPA contain CBI claims. These reports *by definition* deal with records of *significant* adverse reactions. When claims were made, they generally covered all key data elements.

Health and Safety Studies Submitted Under Section 8(d)

Any manufacturer, processor or distributor of a commercial chemical must submit health and safety studies concerning that chemical that it has conducted or that are reasonably ascertainable to it (Section 8(d)). Section 3(6) of TSCA defines a health and safety study as "any study of any effect on a chemical substance or mixture on health or the environment or on both, including underlying data and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this Act."

Section 14(b) of TSCA explicitly precludes claims of confidentiality on these health and safety studies (and underlying data), except where disclosure of the information would reveal processes used in the manufacture, importing, or processing of a substance, or, in the case of a mixture, the portion of the

mixture comprised by any of the substances in the mixture. Any information contained in a study which is clearly personal data (for example, individual medical records), the disclosure of which would invade personal privacy, is exempt from disclosure under FOIA as provided in Title 5, United States Code, Section 552(b)(6). Interestingly, the regulations promulgated by EPA for such submissions (40 CFR 716.55(a)(3)) appear to offer protection for CBI that are *not* included in the statute, in that claims of confidentiality are allowed for company name and address, financial statistics and product codes used by a company.

A large number of health and safety studies (more than 5,000) have been submitted to the EPA under Section 8(d) since 1986, with large peaks in 1987 and 1989 (Figure 9). Prior to 1990, approximately 25 percent of these contain some CBI. When a CBI claim of any type is made, chemical identity is almost always claimed to be CBI (more than 96 percent of the submissions with CBI claims assert such a claim for chemical identity; Figure 10). Substantial numbers of CBI claims were also asserted for submitter identity (provided for in the CFR), use, toxicity, exposure, and environmental release data. The exception is that in 1986 (the first year with 8(d) reporting), a very low percentage of the forms claimed toxicity data to be CBI.

The key point to note is that under the explicit language of Section 14(b) of TSCA, most of these CBI claims are *prima facie* invalid. Congress explicitly intended to make such health and safety data publicly available; doing so represents the entire rationale of Section 14(b). The only claims that Section 14(b) permits are those that disclose "processes used in the manufacturing or processing of a chemical substance or mixture" or, in the case of a mixture, disclose "the portion of the mixture comprised by any of the chemical substances in the mixture." Even under the more lenient language of the regulations (40 CFR 716.55), only company name and address, financial statistics, product codes, and information that "would clearly be an unwarranted invasion of personal privacy." Claims on use, toxicity, exposure, and environmental release data are clearly not permitted either by the statute or by regulations.

CAIR Submissions

The majority of submissions under the Comprehensive Assessment Information Rule (CAIR) were received in 1989 (660), followed by 45 in 1990. Fewer than 30 percent of the original submissions contain any CBI claims, although in almost all cases, it is chemical identity that is claimed as CBI. As CAIR reporting applies to a pre-defined set of chemicals, these CBI claims are curious.

PAIR (8(a) Level A) Submissions

Because data on submissions under the Preliminary Assessment Information Rule (PAIR) are maintained in a separate database, the DAPSS system contains information on only a small fraction of submissions made pursuant to this rule. These submissions, and CBI claims associated with them, are discussed in detail in a subsequent section, in comparison to reporting of comparable information under alternative statutory authority. Accordingly, they are not considered here, except to note that a significant fraction of PAIR submissions contain CBI claims.

Testing of Existing Chemicals (Section 4)

Section 4 of TSCA authorizes EPA to require manufacturers or processors of chemicals in commerce to test the effects of those chemicals on human health and the environment. EPA may exercise this authority by rule only upon a finding that:

- a particular chemical may present an unreasonable risk of injury to health or the environment;
- there is insufficient data available to perform a reliable risk assessment; and,
- testing of the chemical is required in order provide the necessary information. (4(a)(1)(A)

A finding that a chemical may present an unreasonable risk, and a consequent test rule, need not be based upon a finding that a chemical may be toxic, but may rather be based on substantial production and exposure to humans or the environment, in addition to findings of insufficient data and the need for testing (4(a)(1)(B)). A test rule promulgated under Section 4(a) must: identify the chemical, include testing standards for the development of test data, and specify the duration of the testing period.

The key purpose of Section 4 is the generation of studies that address the potential of identified chemicals to have adverse health and safety effects. Accordingly, the results of such studies would be reported to the EPA pursuant to Section 8 of TSCA. However, Section 4(c) provides for applications for exemption from testing that would otherwise be required. EPA has received a significant number of such applications. Because test rules under Section 4 deal with identified chemicals, many of which are in widespread commercial use, it is interesting to consider CBI claims associated with these Section 4(c) applications.

Section 4(c) applications were submitted comparatively rarely between FY 1981 and FY 1986, with a significant increase in the number of submissions in FY 1987 (triple the number from FY 1986), and a noticeable peak in 1989 (Figure 11). This represents another instance of the increasing overall information processing load on OPPT staff. Prior to FY 1987, nearly all such submissions contained CBI claims. When the absolute number of submissions increased, the proportion containing CBI claims dropped considerably (in effect, the absolute number of Section 4(c) submissions with CBI claims has remained relatively constant). Again, it is notable that for a class of submission that deals with already identified chemicals that are generally in widespread use, many of the submissions with CBI claims make such claims for chemical identity.

Hazardous Chemicals Identified under the Act

Once EPA finds that a chemical poses an unreasonable risk to human health or the environment, it has a variety of options under Section 6 to control the commercial use of that chemical. EPA may apply any of these options by rule "to the extent necessary to protect adequately against such risk using the least burdensome requirements." Among these options are two that require the public dissemination of risk-relevant information (emphasis added):

- *requiring that the chemical substance be labelled* with clear and adequate warnings with respect to its use or disposal; and,
- *requiring manufacturers or processors of the chemical substance or mixture to provide notice* of unreasonable risk of injury to anyone who may come in contact with the chemical substance, *to give public notice* of such risk and to replace or repurchase the chemical substance or mixture, whichever is chosen by the person to which this requirement is directed.

One class of chemicals, polychlorinated biphenyls (PCBs), is explicitly addressed in the statutory language of Section 6(e). Section 6 also provided the Administrator with the authority to promulgate rules regulating other chemicals and chemical classes. Much of the Agency's efforts to date have been focused on regulating asbestos (see Appendix D).

Section 6 Submissions

There is no routine reporting to EPA required under Section 6, but OPPT has logged a significant number of documents sent to it under this part of the statute, ranging from 13 in FY 1981 to 202 in FY 1987. As Figure 12 indicates, the number of submissions to EPA significantly increased from 1980 through 1988, with a subsequent decrease in 1989 and 1990. Through 1986, almost all of these submissions contained CBI assertions, but the proportion with such claims has dropped steadily from 1986. Again, a significant fraction of the CBI assertions concern chemical identity (nearly all since 1987). As in the case of Section 4 reporting, this inspires curiosity, because these submissions presumably deal with identified substances that have been the focus of public rulemaking.

Chemical Inventory Reporting

As noted earlier, Section 8(b) of TSCA required EPA to compile, maintain, and publish a list of the chemical substances which are manufactured or processed in the United States. Any substances not listed in the inventory are subject to premanufacture notice requirements under Section 5, and are added to the inventory as they enter commerce. Chemical substances which are manufactured, imported, or processed in small quantities solely for the purpose of scientific experimentation or analysis or chemical research for the development of a product are exempt from reporting to the inventory (40 CFR 710.4 (b)(3)).

The initial inventory was compiled in 1977. Reporting under Section 8(b) provides for CBI claims on the following types of information (40 CFR 710.7):

- company name;
- site;
- chemical identity;
- whether the chemical substance is manufactured, imported, or processed;
- whether the chemical substance is manufactured and processed only within one site and not distributed for commercial purposes outside that site; and,
- the quantity manufactured, imported or processed.

Written substantiation was required for claiming chemical identity as confidential; all other claims could be substantiated by simply checking the CBI box and then attesting to the claims made by providing a signature on the form. To claim the chemical identity as confidential, businesses were required to complete, sign, and submit EPA inventory report Form C (EPA Form No. 7710-3C) (40 CFR 710.5 (b)(7)).

Inventory Data

A review of CBI identification fields in the Chemicals in Commerce Information System (CICIS) indicates that the initial compilation of the TSCA inventory was significantly less affected by confidentiality claims than recent submissions to EPA tend to be. Of the 141,018 records for which information on CBI claims is available (data flags are missing on 3.6 percent of the records), CBI claims

range from a low of 1.8 percent (2,608 records) with the "site-limited" field indicated as CBI, to a high of 27.2 percent of the records (39,742) for which production volume was claimed to be CBI. For most data fields, roughly 10 percent of the records indicate an assertion of confidentiality.

Summary of CBI Claims

Since FY 1982, there has been a massive and increasing number of CBI claims affecting information submitted to the EPA under TSCA. In part, this reflects a nearly exponential increase in the number of documents submitted to EPA under the statute. Much of this increased information load has come through the new chemicals program under Section 5 (PMNs and related submissions), but significant increases have also been seen for substantial risk (Section 8(e)), FYI, and other health and safety related submissions, including health and safety studies submitted under Section 8(d). Even programs that do not require routine reporting, such as the Section 6 regulatory program, have generated large numbers of submissions in recent years. To a lesser extent, the increase in the number of CBI claims reflects changes in CBI claim patterns from the early years of TSCA to more recent times, such as the increase in CBI claims on PMN submissions after the "up-front" substantiation requirements were dropped.

Those submissions under Section 8 that deal with health and safety studies and findings of substantial risk would be expected to have a much lower frequency of CBI claims than do submissions under Section 5, because they are subject to the stricter limitations of Section 14(b). These submissions do have a lower proportion of CBI claims than is seen in the new chemicals program, but there are still a significant number of CBI claims affecting these submissions. This number is far in excess of what might be expected on the basis of the specific limitations imposed by Section 14(b) on CBI claims regarding health and safety studies. For 8(d) submissions, numerous CBI claims are being asserted on data elements (such as chemical identity) that appear to be precluded from such claims under Section 14(b).

The high rate of CBI claims in submissions since 1979 stands in stark contrast to that seen for the data in the original inventory. More than 90 percent of the PMN data are covered by CBI claims, while less than 30 percent of the records in the original inventory are affected by such claims.

CBI claims have decreased in some areas in recent years. For example, claims on submitter identity for PMN, *bona fide*, Section 4(c), and Section 6 submissions decreased between 1986 and 1990. Unfortunately, these decreases in claims on submitter identity have been offset by increasing claims on a more critical data element, chemical identity. A significant concern is the increase in the proportion of 8(e) (substantial risk) notices, and related FYI notices, in which the identity of the chemical is claimed as CBI. Overall, the decrease in some specific claim types is dwarfed by the general increase in CBI claims.

Taken together, the increase in CBI claims in the new chemicals program and the significant numbers of claims affecting other submission types (particularly under Section 8, where the statute restricts claims) suggests that there may be a significant number of CBI claims that are not valid under the statute. The next section of the report addresses the procedures used by EPA to review CBI claims and ensure that they are properly substantiated.

SUBSTANTIATION AND REVIEW OF CBI CLAIMS

As the previous section has shown, the number and scope of CBI claims made for information submitted to EPA under TSCA is extremely large. This huge volume of CBI, taken together with the increases over time seen in CBI claim rates and the relatively high claim rate on submissions subject to the strict provisions of Section 14(b), suggests that a significant fraction of the CBI claims that have been made may not be necessary to protect true trade secret information and may not be valid under the statute.

Although TSCA and its implementing regulations specify explicit requirements regarding the substantiation of CBI claims under TSCA, OPPT does not routinely require submitters to substantiate claims. The penalties for wrongful disclosure are far stronger than those for making invalid claims, and OPPT resource limitations mean that only a small fraction of submissions can be reviewed and/or challenged. Where OPPT has had the resources to challenge CBI claims, these claims are regularly withdrawn.

Statutory Criteria for Reviewing Claims

As specified in its regulations (40 CFR 2.203 *et seq.*), EPA must make a preliminary determination as to whether or not the business information is entitled to confidential treatment when responding to Freedom of Information Act (FOIA) requests, or if it is likely that EPA will be required to disclose the information at a future date. EPA is also authorized to review any claim that has been submitted, in order to ensure that it complies with TSCA and its implementing regulations. Business information is entitled to confidential treatment if (40 CFR 2.208):

1) The business has asserted a claim which has not expired by its terms, nor been waived nor withdrawn;

2) The business has satisfactorily shown that it has taken reasonable measures to protect the confidentiality of the information, and that it intends to continue to take such measures;

3) The information is not, and has not been, reasonably obtainable without the business's consent by other persons (other than governmental bodies) by use of legitimate means (other than discovery based on a showing of special need in a judicial or quasi-judicial proceeding);

4) No statute specifically requires disclosure of the information; and either -
   a) the business has satisfactorily shown that disclosure of the information is likely to cause substantial harm to the business's competitive position; or
   b) the information is voluntarily submitted and its disclosure would be likely to impair the government's ability to obtain necessary information in the future.[6]

When responding to a FOIA request, this determination must be made within a 10 working-day period.

Under 40 CFR 2.205(a) EPA's legal office (defined as the Office of General Counsel in 40 CFR 2.306(e)) is responsible for making the final determination on confidentiality. If a claim is reviewed, EPA offices attempt to obtain the affected business's consent to disclose useful portions of records while protecting the information which may be entitled to confidentiality (*e.g.*, by withholding such portions of

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[6] These criteria apply only to information that has not been explicitly excluded from protection as CBI because the constitute health and safety data (40 CFR 2.306).

a record that would identify a business, or by disclosing data in the form of industry-wide aggregates or totals, or some similar form)(40 CFR 2.202(f)). Under 40 CFR 2.205(f)(2), if EPA determines that the information is not entitled to protection as CBI, then the EPA office taking action on the claim and the Office of General Counsel issues a notice of denial (by certified mail) stating the basis for the determination and that the decision constitutes final Agency action. The information is made available to the public on the 31st calendar day after the date of the business's receipt of the written notice, "unless the EPA legal office has first been notified of the business's commencement of an action in a Federal court to obtain judicial review of the determination, and to obtain preliminary injunctive relief against disclosure" (40 CFR 2.205(f)(ii)(2)). Any prior determinations of confidentiality may be changed due to changes in facts or law, or because the earlier determination was clearly erroneous (40 CFR 2.205(h)).

Statutory Penalties for CBI

As previously noted, the statute assigns no penalties to companies that submit false or invalid CBI claims. Strict penalties are, however, specified for any EPA staff or contractors that reveal confidential information. When TSCA CBI is wrongfully disclosed it is treated as a misdemeanor. Under Section 14 "wrongful" disclosure occurs when an authorized person in possession of CBI material is aware that disclosure is prohibited and intentionally discloses the CBI material to an unauthorized person. Anyone guilty of wrongful disclosure may be subject to a fine of not more than $5,000 and/or not more than one year of imprisonment (Section 14(d)). Wrongful disclosure of CBI by an EPA employee can also be grounds for dismissal, suspension, fine, or other adverse personnel action. Intentional disclosure could also result in criminal prosecution (40 CFR 2.211(c)). The *Code of Federal Regulations* also states that any authorized possessor of CBI must take "*appropriate*" measures to properly safeguard the information and to protect against its disclosure.

Resource Considerations and Actual Practice

Given the vast number of CBI claims received by EPA, it is impossible for EPA staff to review each claim thoroughly to determine its validity, and, at the same time, process the claim in an expeditious manner. The result is that actual practice differs from what the statutory and regulatory language would lead one to expect.

Although the statutory language places the burden of establishing the confidentiality of information upon the submitter, and provides the Agency with the ability to disclose information not properly protected by the submitter, the obligation of the Agency to protect legitimate CBI, and the imbalance in penalties for wrongful disclosure as opposed to invalid claims, has lead OPPT to go to considerable lengths to protect *any* claimed CBI from disclosure. For example, OPPT staff indicate that it is a common practice to review the "sanitized" copies of CBI documents, so that submitters can be notified of inadequate attempts at sanitization, rather than simply placing the sanitized copies in the public docket. While EPA is required to notify submitters of inadequate sanitization it has detected, there is no obligation to examine documents for this purpose.

In practice, except for the 8(d) / 8(e) Challenge Program and challenges at the time a Notice of Commencement is received, the vast majority of claims submitted are not reviewed. Unless OPPT staff have information that leads them to believe the claim is invalid, the claim is not reviewed. Indeed, it is not Agency practice to even request submission of substantiation materials for CBI claims. OPPT employees noted that they generally request substantiation of a CBI claim only when a FOIA request for release of the information has been received. Only when a persistent requestor insists upon release of the data is the submitter contacted to substantiate the claim.

Submitters Amend CBI Claims when Challenged

For the past year, OPPT has reviewed each 8(d), Health and Safety Study, and 8(e), Notice of Substantial Risk submission, and has elected to challenge submitters to substantiate a significant number of CBI claims affecting such notices.[7] Between September 1990 and May 1991, 106 8(e) submissions were reviewed and 52 (49 percent) were challenged. Over the same period, 351 8(d) submissions were reviewed, and 77 (22 percent) were challenged. In essence, *all* CBI claims associated with these submissions have been challenged. The fact that, in *every case to date*, the submitter has amended the submission when challenged, indicates that EPA is correct in challenging the validity of these CBI claims.

In many cases, the invalid CBI claims appear to cover information that is potentially embarrassing to the submitter, but not entitled to protection under *either* Section 14(a) or Section 14(b). Rather, the effort is to prevent disclosure of precisely the sort of information the framers of TSCA wanted made public. For example:

- One submitter claimed its identity, and the identity of the chemical substance, as CBI, because they were concerned that potential customers would interpret toxicity data reported in an 8(e) notice in such a way as to conclude the substance was unsafe (the submitter believed this to be a misinterpretation). Notwithstanding the submitter's desire to put a "spin" on the study, these data, *including* the identity of the chemical, are precisely the sort of information that the framers of TSCA sought to make available to the public.

- In a similar case, the submitter wished to withhold its identity (which included the name of the subject chemical), as well as the chemical identity, because it believed that effects seen in a toxicity study were not compound-related. Again, TSCA explicitly includes the *data* from toxicity studies in its reporting standards, and does not permit regulated persons to submit only *their interpretation* of a study. The submitter of this study had ample opportunity to defend its judgement that the effects were not caused by the chemical, and could have made a convincing case, but instead chose to make an invalid CBI claim.

- In one case, the submitter made a CBI claim on its identity, and that of its trademarked commercial product, on an 8(e) documenting adverse health effects in workers exposed to an apparent breakdown product, produced under unusual circumstances. Again, the submitter could have made public the very limited conditions under which such an adverse effect occurred, as well as the fact that it *appeared to have made diligent efforts to ensure that such effects would not occur again*, and yet instead chose to make an invalid CBI claim.

- Yet another example dealt with a study that identified inadequacies in the medical surveillance program of a submitter. The submitter's identity and plant location were claimed CBI. There seemed to be no evidence that the fact that the submitter used the chemical at that facility was an undisclosed trade secret. Rather, it might reasonably be inferred that the submitter wished to avoid embarrassment regarding the inadequacy of its occupational health program, or to forestall difficulties with its work force.

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[7] Discussions with OPPT staff indicate that a number of factors, beyond the presumptive validity of the CBI claim, are considered in deciding whether or not to issue a challenge. Accordingly, it would not be appropriate to infer that the fraction of CBI claims that is not challenged represents valid CBI claims.

- A recent 8(e) submission, claimed as CBI, was an EPA Order filed under CERCLA. The Order noted, as a Finding of Fact, that a particular facility and its surrounding area had been contaminated by a hazardous substance manufactured by the submitter/respondent. Also noted were the facts that the submitter and others would initiate a cleanup, and that local shellfish had been contaminated. The submitter claimed both company identity and chemical identity as CBI, even though the original EPA Order was not claimed as CBI, and therefore the information was available. Following negotiations, the submitter dropped all CBI claims on chemical identity.

- In another 8(e) filing, a submitter claimed submitter identity and chemical identity as CBI, because it considered the health effect it was reporting to be "highly unusual," and believed that release of the information prior to conducting additional research might cause "premature and possibly unnecessary concern." This represents yet another example of a CBI claim used not to protect commercial information, but rather to conceal exactly the information that Congress intended to make public by way of 8(e) submissions.

- Lastly, a submitter provided the final draft of a study of the effects of working for prolonged periods with particular chemicals. This draft study had been provided to union representatives of the submitter's workers prior to submission to the Agency. Despite the fact that all of the relevant information had thus been made public, the submitter claimed company name, union name, plant sites, and chemical identities as CBI. Following discussions with EPA, the submitter agreed to drop all CBI claims for chemical identities immediately, and to drop all other claims once the final report had been filed with the Agency.

To the extent that these examples are typical, they illustrate an apparent reliance on CBI claims to avoid embarrassment or adverse public reaction, rather than to protect trade secret information from competitors. However, TSCA was enacted precisely to facilitate informed decision-making by the public, such that market forces could lead to the replacement of unsafe chemicals with better alternatives. Invalid claims of the type described above subvert a fundamental goal of the statute.

Although EPA has had tremendous success in challenging inappropriate claims, these challenges have placed strong demands on Agency resources. While some challenges (very few) may require as little as a single five-minute telephone call, others have consumed as much as 40 person-hours. OPPT staff indicate that the majority can be dealt with using two hours of staff time. Thus this effort, dealing with a type of submission of which the Agency generally receives fewer than 200 per year, requires a major investment of effort by OPPT staff. More extensive challenging of submissions does not appear, therefore, to be feasible for all sections of TSCA. For example, there are approximately 10 times as many PMNs as there are 8(e) notices submitted in the average year. At present, OPPT simply lacks the staff resources to challenge all of these. Given the expected massive increase in 8(e) submissions under EPA's "penalty cap," it is not clear that OPPT will be able to maintain its comprehensive challenge program for these submissions.

It is impossible, without an ongoing review of other TSCA submissions, to know the degree to which the pattern of inappropriate CBI claims seen in 8(d) and 8(e) notices is typical of other types of information submitted to EPA. The fact that such claims are made in submissions that explicitly deal with *substantial risk*, however, is not encouraging.

SIMILAR DATA ARE NOT CONFIDENTIAL UNDER RELATED STATUTES

The statutory and regulatory language clearly provide EPA with the ability to deny invalid confidentiality claims. However, they also specify a very broad range of data that *may* be entitled to protection as CBI. This places the Agency in the position of having to decide whether any particular CBI claim is in fact valid. As the preceding section shows, in those instances where EPA has challenged the validity of claims, the claims have proven not to be valid. Without examining each claim individually, it is not possible to conclude that a majority of CBI claims are invalid. However, a comparison of data collected under TSCA with similar data collected under another statute with less liberal confidentiality provisions indicates that CBI claims under TSCA are far in excess of what is needed to protect true trade secrets.

More recent statutes have taken a narrower view than does TSCA of the types of information that are potentially subject to confidentiality claims. For example, TSCA provided EPA all the authority needed to collect information substantially identical to that reported and made public on the Toxics Release Inventory (TRI) under the Emergency Planning and Community Right to Know Act of 1986 (EPCRA) and the Federal Pollution Prevention Act of 1990. However, these latter statutes contain provisions governing public disclosure of the data and information reported to EPA that differ from those in TSCA in important ways.[8]

These differences are apparent when comparing reporting under TSCA's Preliminary Assessment Information Rule (PAIR) with reporting to TRI. Reporting under these two statutes is similar in that 1) both deal with pre-defined sets of chemicals, and 2) PAIR requires reporting on the quantity of chemical lost, while TRI requires reporting on release to the environment. The reporting on releases to the environment for TRI is actually considerably more detailed than the loss reporting required under PAIR.

TRI reporting differs from PAIR reporting in that confidentiality claims for TRI are much more restrictive; claims can only be made for chemical identity, and TRI has explicit provisions to discourage frivolous claims:

- a requirement that the submission be reviewed and signed by a top corporate official;
- a requirement that all trade secret claims be accompanied by information to substantiate the claims, *at the time that they are made*;
- a limitation that only chemical identity can be claimed a trade secret,[9] thereby releasing the rest of the content of the reporting form to the public, including the identity of the claimant and the magnitude of any releases and transfers (thus, there is potential public accountability for any trade secret claims being made);

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[8] Indeed, TRI-like data have been reported for several hundred chemicals under TSCA since the early 1980's, but in contrast to TRI's programs of active public disclosure, the same data under TSCA have been held by EPA in confidential databases.

[9] Under TSCA, it is possible to claim chemical identity as CBI in a submission that is not a health and safety study. Although chemical identity is essential to the full understanding of such studies, it has not been EPA practice to challenge CBI claims on chemical identity, even when the submission was a health and safety study. A few interviewees indicated that precise chemical identity information was not needed to interpret these studies, although the majority did not endorse this view.

- penalties (comparable to those imposed under TSCA on government employees who release TSCA CBI data) for corporate officials making a false trade-secrecy claim under EPCRA.

It is impossible to tell the extent to which each of these four provisions individually is resulting in the insignificant number of claims of trade secrecy under EPCRA. What is clear, however, is that the combination of these four policies results in a dramatic decrease in the number of trade secret claims being received under EPCRA as compared to TSCA. For the 1988 TRI data, there were only 23 trade secret claims, out of more than 70,000 TRI forms.

To obtain a more direct comparison between PAIR and TRI reporting, a subset of 37 chemicals were selected on which reporting was required under both PAIR and TRI, and for which at least one report had been made for both. Using this subset eliminates discrepancies attributable to differences in the particular chemicals subject to reporting. Because PAIR affects a narrower class of potential submitters than does TRI, statistics were obtained not only on overall TRI reporting for these chemicals, but also for submitters who indicated (in the use category of the TRI reporting form) that they were producers or importers of the chemical being reported. Thus, one can be assured that there is significant overlap between the facilities reporting under PAIR and under TRI. Table 1 presents the summary data for these chemicals.

There were a total of 13,164 TRI facility reports for these 37 chemicals in 1988, 463 of which represent producers or importers of the chemicals. As noted above, only a tiny fraction (0.03 percent) of the TRI forms are affected by trade secret claims; even if *all* of these claims affected the 37 chemicals selected, the claim rate would be less than 0.17 percent. If one makes the even less plausible assumption that all of the confidentiality claims not only concern these 37 chemicals, but also were made by producers or importers, the claim rate is less than 5 percent.

For the same set of chemicals, there were 302 PAIR forms submitted. This number is on the same order of magnitude as the number of producers/importers reporting to TRI, although it is substantially lower (35 percent fewer forms). The difference *may* reflect the fact that the threshold quantities for reporting under PAIR are higher than those under TRI; facilities with quantities falling between the two thresholds may account for these missing forms.

Although the *specific* information that can be claimed as CBI on PAIR forms differs from what can be claimed as confidential on TRI forms, these claims can be quantitatively compared as equivalent *types* of information. (On PAIR forms, claims can be made for "quantity lost", while on TRI forms the quantity released must be reported and it is the chemical identity that may be claimed as a trade secret.) Using the subset of 37 chemicals demonstrates that over 50 percent of the PAIR forms had CBI claims. When compared to the TRI confidentiality claims (.03 percent of all TRI forms), the CBI claim rate under PAIR is *more than 1,500 times higher* than the trade secret claim rate under TRI. Even if one makes the very unlikely assumption that all of the TRI trade secret claims are contained on those forms in the subset, CBI claims under PAIR are being made at *10 times* the rate of trade secret claims under TRI.[10]

[10] This is admittedly a wide range of possible claim ratios. The difficulty in narrowing this range arises from the very limited number of trade secret claims made for TRI data. OPPT staff indicated that supplying *any* data on the number of these claims affecting the chemicals used in this comparison might compromise the security of the trade secret data.

These data str , suggest that the CBI claims made under PAIR are far in excess of what is truly required to safegu. trade secrets. They also suggest that if the restrictions on CBI claims under TSCA were tightened to re.emble those of EPCRA, the proportion of submissions affected by CBI claims would drop substantially. Moreover, the comparison above suggests that many of the CBI claims on chemical loss data made under PAIR are no longer valid, if in fact they ever were. The existence in the public record (TRI) of substantially identical information would invalidate the CBI claims.

It may not be appropriate to make a quantitative extrapolation from the analysis of PAIR data to reporting under other provisions of TSCA. However, the data do support the conclusion that CBI claims under TSCA would not meet the requirements for trade secret claims under EPCRA, and that more stringent requirements for substantiating CBI claims could have the effect of reducing the proportion of TSCA data covered by such claims.

LEGAL AND TECHNICAL CONSIDERATIONS

The preceding section illustrates the extent to which statutory controls on frivolous confidentiality claims can influence the number of such claims that are made. Under TSCA's lenient CBI provisions, far more claims are made than under the strict provisions of EPCRA. It has not been demonstrated that the more restrictive confidentiality provisions of EPCRA have resulted in competitive harm to any submitter.

Recent analyses by legal staff in EPA's Office of Pollution Prevention and Toxics indicate that Agency practice in accepting CBI claims has, in fact, been more lenient than the statute (or its implementing regulations) requires. As was noted above, while Section 14(a) of TSCA does not restrict confidentiality claims on a wide variety of information submitted to EPA, Section 14(b) narrowly restricts CBI claims on information from health and safety studies.[11] For such health and safety studies, the only prohibitions on public release of information are on data that disclose "processes used in the manufacturing or processing of a chemical substance or mixture or; in the case of a mixture, releasing any data which discloses the portion of the mixture comprised by any of the chemical substances in the mixture." Moreover, the statute incorporates a broad definition of a health and safety study (TSCA Section 3(6)):

> The term "health and safety study" means any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying data and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this Act.

This language is quite broadly inclusive. Moreover, EPA, in developing regulations on reporting health and safety data, has noted that Congress did not intend to restrict the definition to *formal* studies:

> It is intended that the term (health and safety studies) be interpreted broadly. Not only is information which arises as a result of a formal, disciplined study included, but other information relating to the effects of a chemical substance or mixture on health and the environment is also included. Any data which bears on the effects of a chemical substance on health or the environment would be included. (H.R. Rep. No. 94-179, 94th Cong., 2nd Sess. 58 (1976) (Conference Report), as cited in 47 FR 38782, September 2, 1982.)

Thus, the statute would appear to automatically disallow many CBI claims that have gone unchallenged by EPA until recently. This is particularly true of key data elements such as the identity of chemicals for which health and safety data have been reported under Section 8(d) (health and safety studies) and Section 8(e) (notices of substantial risk). As noted by OPPT attorneys, data that allow a determination of substantial risk inherently meet the statute's definition of a health and safety study. These considerations have lead EPA recently to institute a program of *routine* challenges to CBI claims on these submissions.

The sections of the *Code of Federal Regulations* that implement TSCA follow the statute both in restricting the range of CBI claims that can be made for health and safety studies and in defining such studies broadly. In particular, as OPPT attorneys have pointed out, chemical identity can only be claimed confidential in a health and safety study when the submitter can demonstrate that knowledge of

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[11] The regulatory language implementing these provisions of the statute can be found at 40 CFR 2.203 *et seq.*, and at 40 CFR 2.306.

identity *per se* is sufficient to disclose a process of manufacture or portions of a mixture, a condition that would almost never be true.

Information from health and safety studies is submitted to EPA not only under Section 8 of TSCA, but also under Sections 4 and 5. It is particularly worth noting that since PMNs *must* include any health and safety data known to, or reasonably ascertainable by, the submitter, a substantial fraction of PMN submissions would be subject to the strict CBI provisions of Section 14(b). This would mean that the broad CBI protection currently extended to entire PMN submissions would be dropped from those portions of each submission that constitute health and safety data. Only those PMN substances for which no health and safety data were available would be eligible for the broad protection currently being afforded to all PMNs. This is likely to be a relatively small subset of PMN submissions. Moreover, EPA scientists could easily support the argument that such submissions would be subject to regulatory action under Section 5(e), for lacking adequate information to permit a determination of risk.

There is an explicit exemption provided for data that are not necessary to interpret the health and safety study data. OPPT attorneys have argued that it is *rarely* the case that chemical identity information could legitimately be covered by such an exemption. It is unlikely that any reputable health or environmental scientist could be found who would argue that it is *ever* the case that chemical identity is unnecessary to interpret health and safety data.

This reasoning leads to the conclusion that a significant amount of information that EPA has received over the past decade, and has protected as CBI (cf. Figures 7 and 10), is not in fact entitled to such protection under the statute. It is also true that in order to be protected under Section 14(a) of the statute, the information (from a source *other* than a health or safety study) must be of such a nature that if revealed, it would cause substantial competitive harm to the submitter (40 CFR 2.208).

As noted above, the statistical analysis of CBI claims indicates that many submissions contain multiple CBI claims. One can question the extent to which, in such cases, it is necessary to protect *all* of the information claimed as CBI in order to preserve the submitter from substantial competitive harm. For example, if the key commercial information is that a particular chemical substance has a certain use, one could safeguard this information by claiming *either* the identity or the use as CBI; there would be no need to protect both items of information as CBI.[12] Because EPA has generally lacked the resources to evaluate each submission in the past, it is possible that many of the submissions containing *multiple* CBI claims are in fact making claims beyond those necessary to protect the submitter from substantial competitive harm.

It appears that if EPA applied stricter standards to CBI claims, which could be done under existing regulations, and had the resources to review claims, a significant fraction of the claims would be dropped. It also appears likely that if procedures for submitting CBI claims under TSCA were made more onerous, as they are under other statutes, far fewer CBI claims would be made in the first place.

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[12] As noted above, under Section 14(b), chemical identity is not entitled to protection as CBI when it forms part of a health and safety study.

CONSEQUENCES OF CURRENT CBI CLAIM AND REVIEW PRACTICES

A series of interviews with EPA employees, both within and outside of OPPT, officials in other federal agencies with a potential need for access to TSCA CBI, state government employees familiar with TSCA data, and representatives of non-governmental organizations including environmental groups and labor unions, elicited a wide range of opinions on both the nature and extent of the problems posed by TSCA CBI practices. In general terms, interviewees tended to concentrate on two separate problems posed by current CBI practices. Those within OPPT were generally, although not exclusively, concerned primarily with the *volume* of CBI, and its implications for the use of their limited resources. Those outside of OPPT were primarily concerned with more limited data sets that CBI claims had rendered unavailable to them. In order to address the concerns identified by OPPT staff, a significant reduction in the absolute number of CBI claims would be required. For outside data users, concerns could sometimes be addressed by eliminating CBI claims on a very limited data set (*e.g.* claims on chemical identity in Section 8(e) notices). The particular data set for which declassification was desired varied among the interviewees.

CBI Presents a Logistics Challenge for EPA

CBI Security Procedures are Strict

The statutory language of TSCA, and the regulatory language implementing it, specifies the types of information submitted under TSCA that can be claimed as CBI, as well as the circumstances that determine the legitimacy of CBI claims. Neither the law nor the regulations, however, contain any detailed information regarding procedures employed to safeguard TSCA CBI. These are covered by guidance documents developed by OPPT.

These guidance documents, and the procedures described in them, were developed in the context of two lawsuits brought against EPA by Polaroid Corporation, which were settled in 1985 by means of consent agreements. The consent agreements incorporate the security requirements in the guidance documents by reference, and require that adequate public notice be given by the Agency prior to implementing any significant changes in security procedures, and contemporaneously with the implementation of any substantive changes.

The guidance documents developed by EPA establish a controlled environment for TSCA CBI material to ensure that a complete audit trail remains as to the location of any document at all times and the identity of the person responsible for the document if it has been removed from the Confidential Business Information Center (CBIC). Appendix E describes the procedures which EPA staff, contractors, and subcontractors must follow to safeguard CBI material. It is the consensus of the EPA staff interviewed for this report (including several staff involved in developing CBI security procedures) that the level of protection provided for TSCA CBI is equivalent to that provided to information deemed "secret" for national security purposes. Thus, the level of protection afforded TSCA CBI exceeds any reasonably foreseeable threat.

CBI Security Practices are Effective

There is ample evidence that CBI security provisions are quite effective in preventing the release of CBI. No case has been documented in which CBI was intentionally disclosed, and the number of cases of accidental disclosure is quite limited. Fewer than two dozen instances were identified in which procedural violations were of such a nature that they were likely to result in disclosure of CBI to unauthorized persons, such as mailing materials containing CBI to the wrong submitter or discussing CBI

at a public meeting (details are provided in Appendix E). No one has ever demonstrated that any competitive harm has come to any submitter from the disclosure of CBI. It has been argued, both by EPA staff and outside observers, that the degree of protection afforded to TSCA CBI is, in fact, disproportionate to the threat of wrongful disclosure. As noted below, EPA is exploring options to decrease unnecessary burdens on users of TSCA CBI, without lessening protection against *realistic* threats to CBI security.

CBI Security Entails Direct and Indirect Costs

Safeguarding information subject to CBI claims imposes significant costs on EPA's Office of Pollution Prevention and Toxics, including staff efforts involved in CBI security procedures, whether directly or by requiring extra efforts in processing information that is needed to perform regulatory review, as well as explicit expenditures for security, duplicative information systems ranging from PCs to mainframe computers, and extensive background investigations on individuals who must have CBI access to do their work.

It is difficult to quantify the costs to EPA of CBI security provisions, as many of the expenses entailed in maintaining CBI security are not accounted separately by OPPT. In addition to security staff, Document Control Officers, and Document Control Assistants within OPPT at EPA headquarters, staff in the regional EPA offices and EPA laboratories devote significant efforts to ensuring the security of TSCA CBI. No separate rental figures are available for office space used to provide CBI secure areas, nor is there separate accounting for CBI-approved storage containers, special locks and electronic access control systems, or duplicate computer systems and computer security software. Neither is it possible to quantify the cost of not being able to use low-cost grantee workers for tasks involving CBI.

Moreover, CBI imposes significant changes in the work environment of OPPT staff. Routine work activities such as casual "hallway" discussions with colleagues, reviewing documents while riding the Metro to work, taking notes at meetings, or writing a memo on the common office word-processor become essentially impossible when CBI is involved. Instead, discussions must be held (only with colleagues who have CBI clearances for the particular section of TSCA) in secure areas where there is no chance of being overheard, documents can be reviewed only in secure environments, meeting notes themselves become CBI documents and must be logged and guarded under lock and key, and computers must have their memories and permanent storage media over-written after processing CBI. Even typewriter ribbons must be secured until they are destroyed.

The internal cost savings that EPA could realize with respect to its regulatory efforts from decreased CBI claims under TSCA depend critically not only on the extent of any reduction in claims, but also on the patterns of reduction. An illustrative example is provided by the new chemicals (PMN) program. As has been shown above, most PMN submissions entail multiple CBI claims. It does not appear to be unusual for a PMN to have half a dozen or more CBI claims. If each such document contained only a single claim (a reduction in total claims of more than 80%), the document would still have to be protected using procedures substantially similar to those that would apply without any decrease in CBI claims. Only in the case where substantial numbers of PMN submissions were *entirely* free of CBI claims would a reasonable possibility exist for freeing staff and resources from CBI procedures.

The situation seems more hopeful in other program areas, where a smaller fraction of submissions are affected by CBI claims. In these programs, any substantial reduction in the proportion of submissions affected by CBI claims might enable the program to be run in a manner generally free of CBI considerations and constraints; a small subset of program staff and facilities could address the limited number of CBI-tainted submissions.

OPPT is Improving its Efficiency in Processing CBI

In addition to its efforts to reduce the amount of information for which invalid CBI claims are made, OPPT has initiated several efforts to increase the efficiency with which it processes CBI material, and thus reduce the burdens imposed by the need to safeguard CBI. For example, a pilot program is exploring the use of an optical disk information storage system that would enable OPPT staff to review submissions with fewer paper documents. This would both facilitate efforts to track access to CBI, and reduce the risk of inadvertent disclosure through misplacement of documents. OPPT is also negotiating with industry to have submitters prepare all of the copies of CBI documents that OPPT requires for its review process. This would reduce the equipment and staff costs involved in assuring security while copying CBI materials.

EPA is exploring possibilities for reducing CBI security procedures that do not provide meaningful protection against realistic threats of CBI disclosure. For example, encryption of data exchange lines for Local Area Networks (LANs) contained entirely within space controlled by EPA may not be required, even if such data lines pass through areas that have not been designated as CBI secure areas; the protection provided by dedicated electrical conduits is considered sufficient. The threat of an intruder being able enter EPA-controlled space, tap into such data lines, and obtain meaningful disclosures of CBI, is simply not a realistic one.

EPA is strongly considering changes in its procedures that would facilitate granting employees and contractors access to TSCA CBI submitted under several sections of the law. While the Polaroid consent decree requires that access to TSCA CBI be granted on a section-by-section basis, the nature of information review involved in administering OPPT regulatory programs is such that most staff will require access to information submitted under multiple sections of TSCA. For example, a routine feature of PMN review by the Agency is a search of 8(e) and FYI submissions for risk-relevant information on compounds that are structurally similar to the PMN compound. Procedural changes in this area could eliminate considerable unnecessary administrative overhead.

EPA Costs Associated with Invalid CBI Claims

Interviews with EPA staff revealed a variety of perceptions regarding both the proportion of CBI claims that are invalid under TSCA and the impacts of such invalid claims on EPA's effectiveness in administering the law. Some asserted that invalid claims were a serious problem, with a number of outrageous abuses occurring, while others maintained that CBI requirements were serving as a scapegoat for overall OPPT resource limitations. Interviewees also expressed a wide variety of views on the extent to which CBI procedures reflected the institutional culture of EPA, as opposed to being required by the statute.

In general, opinions on the number and consequences of invalid CBI claims tended to be correlated with each interviewee's role in the CBI process. Those involved in the promulgation of regulations regarding CBI, or in implementing procedures to ensure the security of CBI, were more likely to be convinced that the bulk of CBI claims were legitimate, and to minimize the adverse impacts associated with invalid claims. OPPT staff who required access to CBI in order to review the risks posed by chemicals were far more likely to consider the number of claims excessive, and to relate cases of egregiously inappropriate CBI claims. Their views were shared to a considerable extent by OPPT staff involved in efforts to disseminate data to other federal agencies, state governments, and the public.

Another area where a wide range of opinions existed concerned the utility of generic information supplied for public dissemination when specific information was claimed as CBI. To some extent this varied according to the type of information; it also reflected the quality of the generic information

supplied. For example, a number of interviewees (although not all) indicated that adequate generic chemical identity information would be almost as useful as specific chemical identities that are generally covered by CBI claims; however, almost all indicated that the generic chemical identity information currently supplied by most submitters was essentially useless. A significant number of interviewees indicated that for data on environmental releases, production volumes, and other exposure-relevant information, order-of-magnitude range estimates might be nearly as useful as precise values.

As noted above, the available evidence indicates that many CBI claims were invalid at the time they were asserted. A somewhat different problem is presented by claims that were legitimate at the time they were asserted, but that have been rendered invalid by subsequent events. There was a widespread consensus among interviewees that this description might apply to a significant fraction of the material being safeguarded as CBI by EPA. Although opinions differed regarding the extent to which one could establish, *a priori*, a sunset or limitations provision for such claims, there was consensus that many CBI claims would be dropped if there were an ongoing cost to asserting the claim.

Availability of Data Outside OPPT

Over the life of TSCA, there have been repeated criticisms of the fact that much of the data collected under the Act are unavailable outside of OPPT. The TSCA regulatory process has been denounced as being closed to effective outside scrutiny. Thus neither the public at large, nor relevant interest groups, have confidence in the TSCA regulatory process. One indicator of this level of dissatisfaction with TSCA was the public protest that accompanied EPA's attempt to commemorate the tenth anniversary of TSCA's passage.

Another criticism of TSCA CBI is that it hampers the dissemination of important information that has been submitted to EPA under TSCA to regulatory authorities outside of EPA. The statute clearly provides for the provision of TSCA data to other federal officials for the purpose of protecting health and the environment or law enforcement (Section 14(a)(1)). However, the operating principle appears to be that such officials will get such data only if they request it; they are not notified by EPA that information relevant to their duties has been submitted under TSCA. Moreover, OPPT has been insisting that such officials be explicitly issued CBI clearance. This criticism applies not only to other federal agencies, but also to other program offices within EPA.

Other Offices Within EPA

Few of the EPA staff outside of OPPT have any familiarity with data available under TSCA. Moreover, because there are significant difficulties associated with obtaining CBI clearance and handling CBI data, even those EPA staff outside of OPPT who are aware of the data attempt to make use of them. This includes regional staff, enforcement officials, research scientists, and toxics regulators in the other program offices.

Other Federal Agencies

Requests for TSCA CBI by federal officials outside of EPA appear to be limited. This appears to represent two key factors. The first is lack of knowledge that OPPT is in possession of the information. This was commented upon principally by OPPT staff, who noted that there were no mechanisms in place to facilitate data passing on a routine basis. Interagency coordination groups, such as the one for

OSHA, NIOSH[13], and EPA (ONE) address TSCA policy issues, but do not serve as clearinghouses for distribution of submissions among the agencies.

The second factor limiting access by other federal officials to TSCA CBI is the requirement that the officials receiving the information continue to give it the same level of protection afforded by OPPT. As one OSHA official noted, some information would be entirely useless to his program if he were not in a position to disseminate it. This official reported several attempts to obtain TSCA CBI, all of which were unsuccessful, because some of the information would be incorporated into a public document. In fact, this official would have been able to use generic or categorical reports, rather than the specific data that EPA had collected as CBI, but was unable to obtain such information. This official was particularly struck by the fact that OPPT staff appeared to be far more concerned with protecting CBI than with disseminating information that the statute enabled it to share.

An official in another part of OSHA noted similar problems in obtaining TSCA CBI. In the course of a major rulemaking effort (promulgation of Permissible Exposure Levels), this official sought exposure-related information possessed by OPPT. Although several OSHA staff members obtained clearances for access to TSCA CBI, OSHA logistics precluded establishing facilities that met the security requirements for TSCA CBI within their offices. Accordingly, OSHA staff were only able to review TSCA CBI within the confines of the Confidential Business Information Center at EPA.

More importantly, in order to support its rulemaking efforts, OSHA deemed it necessary to publicly disclose exposure-related information, which would clearly have contravened the CBI provisions of TSCA. In the end, OSHA was forced to conduct an independent survey of a sample of 6,000 firms, in order to obtain data that were already in EPA's possession. The survey obtained a response rate of between 60 and 65 percent, leading the OSHA officials to conclude that a substantial fraction of the TSCA CBI they had sought was not, in fact, trade secret information being protected from disclosure. This finding is consistent with the comparisons noted above, in which data that have been claimed CBI under TSCA have been made public in other contexts, and the fact that EPA's CBI challenge efforts have had such a high success rate.

A NIOSH official reported experiences similar to those of OSHA. Like OSHA, NIOSH has been able to obtain TSCA CBI access for its staff, but the differing security procedures for trade secrets under its regulations have precluded NIOSH from taking possession of TSCA CBI. NIOSH officials indicated that they obtained duplicative reporting from industry, using NIOSH trade secret provisions, of information that had been submitted to EPA as CBI. In another case, serious conflicts with TSCA CBI provisions were avoided because NIOSH decided not to publish guidance documents. NIOSH would have been unable to publicly divulge the rationale for the guidance, because it was based on TSCA CBI.

The NIOSH official also noted a successful collaborative effort with EPA, OSHA, and a chemical manufacturer on a chemical that had been the subject of an 8(e) notice to EPA. Joint meetings of all parties enabled the various agencies, *with the cooperation of the manufacturer*, to achieve a mutually satisfactory outcome. However, the NIOSH official noted that if the manufacturer had not been cooperative, NIOSH would have had serious difficulties in discharging its responsibilities. No mechanism is in place to deal with such situations; a draft Memorandum of Understanding addressing such cases was apparently dropped when the specific situation was resolved.

[13] The National Institute of Occupational Safety and Health

State Governments

State environmental programs are at least as diverse as those of EPA. As a result, they have diverse needs for information on potentially toxic chemicals. With the exception of data on chemicals that are submitted to EPA prior to the introduction of the chemical into commerce, there is no reason to believe that any of the data collected under TSCA would be in any way less relevant to state environmental officials than to EPA staff.

The statutory language of TSCA provides an explicit, and very limited, specification of the persons to whom TSCA CBI may be disclosed; state officials are clearly not among those covered. Recognizing these constraints, OPPT has established a Chemical Desk to attempt to meet the needs of state (and regional) officials seeking information on chemicals.

State officials provided a wide range of opinions regarding the extent to which their inability to obtain TSCA CBI impeded performance of their duties. Most indicated that they had not attempted to obtain TSCA CBI; some indicated that this reflected the fact that they did not need the data, while others indicated that they did not expect to receive the data they needed.

Those state officials who indicated that they were satisfied with their ability to obtain information that OPPT holds as TSCA CBI were primarily concerned with obtaining toxic hazard data in order to respond to accidental releases or spills of chemicals. They generally reported receiving the information as voluntary submissions from companies to the responsible state health or emergency response officials. Others noted that state laws provided a mechanism to obtain data comparable to that submitted to EPA under TSCA. It was noted as a source of potential concern, however, that state enforcement personnel dealing with hazardous waste or water discharges, for example, would *not* be able to get this sort of data. Officials were quite concerned that EPA might be setting environmental discharge conditions for chemicals at various facilities, but not informing state officials responsible for monitoring discharges to the environment.

One state official expressed extreme frustration over his attempts to obtain toxicity information and related data from health and safety studies from OPPT. He indicated that OPPT staff were completely uncooperative with his requests for information, citing CBI requirements, despite the fact that his state's trade secret provisions were as protective of confidentiality as those for CBI under TSCA. In the past, his state has presented data-sharing plans to Congressional oversight committees, although this effort was abandoned when TSCA reauthorization did not proceed.

Environmental Groups

Few attempts have apparently been made by public interest organizations to obtain data submitted to EPA under TSCA. Records of FOIA requests maintained by OPPT indicate that the overwhelming majority of such requests have come from chemical companies and law firms that frequently represent such companies. Relatively few requests have come from public interest organizations such as environmental groups, or from other concerned parties such as labor unions. OPPT has presumed, and there seems little reason to doubt, that the FOIA requests from chemical companies and their representatives probably represent an attempt to obtain information that would provide the requestor with a competitive advantage.

Representatives of several nationally prominent environmental groups related their experiences with TSCA and TSCA CBI. Most of these environmental groups indicated that they had never sought information submitted under TSCA. The comment was frequently made that TSCA played little role in any of their activities, particularly in comparison to the Clean Air Act (CAA), Clean Water Act (CWA),

concerns, but rather the fact that EPA was not routinely distributing all of the non-CBI information in 8(e) submissions to them, as the Agency apparently had in earlier years. Of greatest concern, however, was the lack of specific data covered by CBI claims, particularly the identification of specific chemical identities, uses, or plant sites. This was judged key data to enable labor organizations to identify potential risks to their members.

The labor organization officials, like the state government officials, did indicate that if they received information to alert them to a potential problem, they had means to obtain the data they required independent of TSCA. These included specific provisions of collective bargaining agreements, threats of action before the National Labor Relations Board, and threats of adverse publicity. Only one case was identified in which an attempt was made to obtain CBI from EPA. In that case, the organization had learned that a particular chemical had adverse health effects not reported on its Material Safety Data Sheet. The union wanted to determine if the chemical had been included in the TSCA Inventory, but the data were denied, because the union could not establish a *bona fide* intent to introduce the chemical into commerce.

EPA Rulemaking (Asbestos)

As noted in the popular press, EPA's regulations on asbestos have recently been remanded to the Agency, reflecting a judicial finding that the Agency's approach to regulation did not adequately consider less burdensome alternatives. Less widely known is the fact that asbestos was the *first* chemical, other than those specifically mentioned in statutory language, to be considered for regulatory action under TSCA.

Ten years ago, EPA required industry to report on uses of asbestos; large volumes of data have been entered into a database. Such a large fraction of the data were claimed as CBI, however, that EPA has maintained the entire database as confidential.

In the nearly fifteen years that this regulatory effort has been under way, public participation has been minimal, reflecting the fact that EPA has been unable to publicly release the analytical documents that support its regulatory decisions, particularly with regard to asbestos economics and potential substitute materials. This situation clearly illustrates the "infectious" nature of CBI, in that even government-conducted analyses that rely on CBI materials themselves become CBI. It further demonstrates the potential for CBI claims to have fundamental impacts on the regulatory process, precluding effective public oversight.

EPA Efforts at Data Distribution

OPPT has recently initiated the "Going Public" program, in an attempt to make its regulatory activities more accessible to, and better understood by, the public. In many ways, this program offers the promise to mitigate, if not eliminate, some of the criticisms that have been made of TSCA over the past decade. OPPT staff charged with making public presentations, however, have noted that the Agency's own efforts to be open with regard to its regulatory activities are being frustrated by CBI claims. A particular case in point that was noted concerned the attempt to place a meaningful RM1[14] summary in the public docket, for a chemical with very high aquatic toxicity, when the identity had been claimed as CBI. The generic name provided for the compound was so generic as to be useless. Several OPPT staff

[14] Under the OPPT "going public" program, this represents an initial summary public report on actions taken by the EPA to control a chemical risk.

Safe Drinking Water Act (SDWA), Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund), the Superfund Amendments and Reauthorization Act (SARA), the Resource Conservation and Recovery Act (RCRA), and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Interestingly, nearly every environmental group referred us to a single group, and a single individual within that group, as the person to discuss TSCA. One other group did have fairly extensive experience with the PMN program, but only with respect to biotechnology submissions. Another interviewee noted that it had, on one occasion, requested data from a study of dioxins in 104 plants, and that OPPT staff had been instrumental in getting CBI claims attached to the study withdrawn.

The environmental group involved in reviewing biotechnology has submitted a significant number of FOIA requests to EPA regarding PMNs. The interviewee noted that EPA staff had been very cooperative, but that the nature of the FOIA process, coupled with the fact that EPA does not request substantiation of CBI claims on PMNs *until* a FOIA request is received, meant that up to three years could pass before information needed to evaluate the PMN was received. Meanwhile, EPA's review process had been completed, and in many cases the environmental release of genetically engineered organisms had occurred. Thus, the process precludes any effective outside oversight of EPA's decision-making process. The interviewee noted that in many cases, the PMN submitters had voluntarily supplied desired data to the environmental group, because it was in their interest to do so, in order to avoid adverse publicity. It was noted that there was, at present, no effective alternative to reliance on the cooperation of PMN submitters.

The group (and individual) with the most TSCA experience, to whom all the other groups directed us, indicated that it had essentially dismissed TSCA as a meaningful environmental statute, unless significant changes were made in re-authorizing the Act. This group had had little involvement with TSCA since 1988. For this group, CBI was only one concern among many regarding the effectiveness of TSCA. Others include the fact that TSCA does not require even minimal safety testing for new chemicals entering commerce, leading EPA to rely on highly speculative structure-activity predictions, and, in particular, the susceptibility of TSCA's "unreasonable risk" standard which is subject to a variety of distortions from "cost-benefit" analyses (EPA has recently encountered this problem itself, with respect to the remand of its asbestos rulemaking).

Among the specific *CBI* concerns noted by this interviewee was the fact that the group could not provide meaningful public comment on EPA's proposed asbestos phaseout rule (see below). It was also noted that EPA's decision to seek substantiation of CBI claims only after a FOIA request was received had lengthened the FOIA process to the point of ineffectiveness. The interviewee also noted that EPA had, in promulgating CBI regulations, given an extremely broad definition of acceptable CBI claims under Section 14(b).

Labor Organizations

Discussions with health and safety officials in organized labor indicated that, as in the case of environmental groups, little reliance had been placed on TSCA to supply the information needed to protect their members from risks posed by chemicals. Unlike the environmentalists, however, labor representatives appeared to be more specifically concerned with information affected by TSCA CBI. In particular, each of the labor officials focused on the 8(e) program as particularly bearing on the concerns of their members. Some also indicated a concern with PMN chemicals, including R&D chemicals, to which their members might be exposed.

Each of the labor representatives commented that the publicly disseminated information from 8(e) submissions did not contain sufficient information to be useful to them. In part, this did not reflect CBI

chemicals, the United States (and the EPA) has primary responsibility for obtaining data on 20 chemicals (9 Phase I and 11 Phase II); the specific chemicals are listed in Appendix F.

A second list of chemicals for which health and safety information is critical is represented by known human carcinogens. The *Fifth Annual Report on Carcinogens* (NTP 89-239), produced by the National Toxicology Program in 1989 (the most recent such report available at the time of the study), lists 11 such chemicals or chemical classes (also listed in Appendix F).[15] The fact that these chemicals are known to cause cancer in humans, while sufficient to identify them as being of great concern, does not indicate that they are adequately characterized for health risks. A great deal of additional information is needed to reliably predict risks from specific exposures.

Both lists of chemicals were submitted to OPPT, requesting data on the total number of 8(e) and 8(d) submissions regarding the chemicals, as well as on CBI claims affecting these submissions. This information request only addresses a small subset of the data collected by OPPT; consequently, it is possible that EPA has additional information on these chemicals beyond that which was requested. While this information request could fail to locate a significant fraction of the information on these chemicals in EPA's possession (both CBI and non-CBI), any information that was identified by this search request would be critical to assessing the risks posed by these chemicals. Moreover, this search focuses on submissions for which CBI claims would be covered by the strict provisions of Section 14(b).

EPA's search retrieved two Section 8(e) submissions, one each for a carcinogen (benzene) and a SIDS chemical (octamethyl cyclotetrasiloxane). Neither of these had any associated CBI claims. More strikingly, the search produced 60 Section 8(d) submissions concerning five of these chemicals, two carcinogens (asbestos and benzidine) and three SIDS chemicals (octamethyl cyclotetrasiloxane, methyl ethyl ketone, and methyl isobutyl ketone).

For asbestos, there have been five 8(d) submissions. For three of these, *all* key data fields were flagged as CBI. For benzidine, there were three 8(d) submissions, *all* of which had *all* key data fields flagged as CBI. For octamethyl cyclotetrasiloxane, there were 30 8(d) submissions, three of which had CBI claims, only one of which claimed CBI for all fields. For methyl ethyl ketone, there were 19 submissions, two of which claimed CBI. None of the three submissions on methyl isobutyl ketone contained CBI claims.

It is notable that for a list of only 31 chemicals with high priority data needs, EPA was already in possession of health and safety data submitted under Section 8(d) on five. If this success rate applied to all 147 SIDS chemicals, one would predict that EPA had health and safety data on more than 20 chemicals. Moreover, the Agency received several submissions on most of these chemicals, and fully 30 submissions on one. Although the majority of the Section 8(d) information held by EPA on these chemicals is not covered by CBI claims, a significant fraction (nearly a fifth of the submissions) is. This indicates that CBI claims on health and safety studies, many of which appear to apply to material excluded from CBI protection under Section 14(b) of TSCA, are preventing EPA from disseminating data for which the international community has identified a pressing need.

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[15] Hexavalent chromium is one identified human carcinogen; this represents chromium in a particular valence state, rather than a specific chemical compound. The report lists six hexavalent chromium compounds as being of particular importance.

expressed the view that being forced to present such incomplete information to the public was damaging to their scientific credibility.

Limits on Information Dissemination Under TSCA

The interviews conducted for this study clearly indicate that CBI concerns have limited the effectiveness of TSCA as a means of disseminating information on the risks posed by chemicals in commerce. The interviews do not indicate a crisis in the availability of TSCA CBI outside of EPA, *primarily* because the organizations contacted had *independent means* of obtaining the data that they sought. The ability of these organizations to obtain, by other means, information that is held as CBI under TSCA suggests that EPA is protecting this information unnecessarily. In some of the cases discussed above, the information was made publicly available, indicating that it was not, in fact, CBI. In other cases, the more stringent security provisions provided for TSCA CBI, relative to the trade secret provisions of the Occupational Safety and Health Act, various state laws, or even voluntary confidentiality agreements, appear to provide more protection than is deemed necessary by the submitters of the data. Moreover, these distinctions between the security provisions of TSCA CBI and those of other legal authorities have lead to an increased burden on industry, in the form of duplicative data submissions.

However, while state and federal agencies and organized labor do appear to have access to considerable amounts of data classified as CBI under TSCA, they still indicated concerns regarding the reliability of these alternative means of obtaining CBI. They also noted the possibility that they simply were not becoming aware of data submitted under TSCA that would be of critical concern to them if they knew of its existence.

Finally, it should be noted that the general public *does not* have these alternative means of obtaining access to information that is claimed as CBI under TSCA. This is of concern not only as it relates to the intent of the framers of TSCA, but also as it may have an adverse impact on EPA's credibility in regulating risks under its TSCA authority.

Missed Opportunities

Another approach to determining whether CBI claims under TSCA are interfering with the dissemination of information that is needed to protect human health and the environment is to compare data held by EPA as CBI under TSCA with key data needs identified by EPA and other authorities. This study identified two sets of chemicals with such critical data needs; reports were requested from EPA both on relevant data submitted under TSCA and on the extent to which such data is affected by CBI claims.

One of these sets of chemicals comes from the SIDS (Screening Information Data Set) list of chemicals compiled by the Organization for Economic Cooperation and Development (OECD). The EPA represents the United States on the relevant OECD Working Group. These 147 chemicals (53 in Phase I and 94 in Phase II) were selected by OECD because:

1. Each is produced in an OECD member country in quantities exceeding 1000 metric tonnes per year, and
2. There is little or no available safety data for each chemical.

The goal of OECD is to collect and/or generate data on risks to human health and the environment posed by each of these chemicals, so as to assess their risks by the end of 1993. Of this list of 147

STRATEGIES FOR REDUCING THE IMPACTS OF INAPPROPRIATE CBI CLAIMS

The language of the Toxic Substances Control Act allows broad classes of information to be claimed as CBI, and places the burden on EPA to challenge invalid claims, even those that appear to directly contradict statutory limitations. In order to issue and sustain such challenges, EPA must go through a series of time consuming and labor intensive steps. This inherent bias of TSCA, favoring the protection of invalid claims over the risk of disclosing truly confidential information can only be fully addressed by Congress.

While EPA has some administrative discretion under TSCA, any attempt to use it to reduce the number of unnecessary CBI claims on submitted information must confront the bias of the current statute in favor of the CBI claimant. For submissions that do not qualify as health and safety studies covered by Section 14(b), any information deemed confidential by the submitter must be individually challenged, a condition that contrasts markedly with the trade secret provisions of more recent statutes. Thus, for any such claim, EPA must at least notify the submitter that it intends to deny a CBI claim, and consider attempts by the submitter to substantiate the claim. While it can be argued that EPA has, until recently, made it easier than necessary for submitters to assert CBI claims, it remains true that when EPA challenges a CBI claim, it must match or exceed the efforts expended by the submitter in defending the claim. Under the current statutory language, the ability of industry to generate meaningless or boilerplate "substantiation" will always exceed EPA's ability to review such materials.

Congressional Options

Class Determinations

One of the most direct approaches to resolving the imbalance produced by the current statutory requirement for EPA to consider each individual CBI claim, regardless of merit, would be to grant EPA the authority to make class determinations of what will and will not be accepted as CBI and/or the nature of the substantiation that is required for different types of data. This would enable the Agency to preclude frivolous or clearly invalid claims at the time of submission. Without such authority, EPA is relegated to chipping away at the deluge of CBI claims with a series of narrow ad-hoc actions to declassify information after the fact. To the extent that Congress has not provided explicit statutory guidance, EPA would presumably make its own class determinations with notice and comment.

Adopt the Successful EPCRA Trade Secret Framework

As noted above in the comparison between reporting under TSCA and EPCRA, the stringent requirements for asserting trade secret claims under EPCRA have lead to a much lower claim rate than that seen for TSCA CBI, and have not caused submitters to be harmed by disclosure of truly confidential information. The key distinguishing features of EPCRA are:

- "Up-front" substantiation (*i.e.* at the time a claim is asserted)
- Signed by High Level Official
- Significant Penalties for False Claims
- A narrow definition of allowable claims, with a requirement for disclosure of generic information on claimed information (so the public knows what is covered by confidentiality claims).

EXCESSIVE CBI FRUSTRATES THE INTENT OF TSCA

The legislative history of TSCA presented earlier in this report, and the statutory language of Section 14(b), make it quite clear that Congress intended to limit CBI claims with respect to information bearing on health and safety concerns. Until very recently, EPA practices provided CBI protection as a matter of course, rather than routinely reviewing claims to ensure that they could be substantiated. Indeed, entire classes of data that appear to be denied protection under statutory language have been treated as CBI. With the exception of the recently initiated process for reviewing 8(d) and 8(e) claims, the only meaningful check on CBI claims is the goodwill of submitters.

Vast amounts of data covered by CBI claims have been collected by EPA over the past decade. As indicated both by EPA's recently initiated challenge effort and by comparison to reporting under other statutes, many of these CBI claims appear to be invalid. This huge quantity of CBI data has imposed significant transaction costs upon EPA.

Attempts to find persons or organizations outside of OPPT that are making any significant use of TSCA data have proven unsuccessful. Most individuals, inside and outside of government, who indicated that they had attempted to obtain TSCA data from OPPT noted that they had been frustrated in their efforts. It is reasonable to conclude that the (realistic) perception that it is difficult to obtain data that have been submitted to EPA under TSCA is a significant factor in the failure of TSCA to serve as a means of disseminating information on the risks posed by toxic chemicals. Some of the data held as CBI by EPA are needed to meet pressing demands for health and safety information on chemicals with high exposure potential.

The lack of access to TSCA CBI outside of OPPT has potentially detrimental effects on public health and safety in several ways. First, there is no way for the outside scientific community to review the risk assessment decisions made within OPPT. While there is no reason to doubt the competence of OPPT scientists, limited data access results in limited review. As an example, the structure-activity prediction methods used by OPPT scientists depend to a significant extent upon CBI data; they therefore can not be fully evaluated by outside scientists. Neither can an outside organization elect to test OPPT hazard and risk predictions, because the information needed to select appropriate chemicals and toxicity testing methods is covered by CBI claims.

Other organizations, inside and outside of government, that could play a significant role in reducing exposures to and risks from toxic chemicals, do not receive relevant information from OPPT. Thus, OSHA is not provided with information in a form it could use for promulgating worker protection standards, and labor unions are unable to warn their members or to raise toxicity concerns in the context of collective bargaining. Consumer and environmental groups are not able to address specific toxic chemicals to which may threaten human health or the environment.

Lastly, current procedures for implementing TSCA CBI have not provided, to the individual citizen, in Senator Hartke's words: "the right to know what is in store as far as the toxicity of chemicals is concerned."

Such an approach, under Section 14(b) of the current statute, would enable EPA to release much of the information of greatest interest to other agencies (federal and state) and the public, namely risk-related information *directly* associated with a specific chemical. It is possible that industry would respond with blanket assertions that chemical identity reveals processes. In this case, EPA would need knowledgeable technical staff in numbers sufficient to counter such a paper onslaught. EPA remains under obligation to notify the submitter individually in advance of CBI disclosure, if the submitter responds to a request for substantiation.

EPA could take a similar stand with regard to other categories of information that it does not believe to be entitled to protection as CBI. In addition, it would be wise to identify those additional classes of data which have a significant probability of not being sustainable as CBI (*e.g.* the identity of a chemical no longer produced by the submitter or exposures to a chemical more than five years ago.)

While development of such a framework may take some effort on the part of OPPT, such a framework can be used by the Agency as part of any discussions with industry (see below), to guide challenges by the staff, and develop other policies (*e.g.* fees [see below]). Moreover, EPA should be prepared with such a policy viewpoint should Congress decide to make some class determinations on a statutory basis.

"Jaw Boning"

Through programs such as 33/50 and the Air Toxics Voluntary Reductions Program, EPA has demonstrated the potential for effective voluntary actions on the part of industry. Industry groups have also made public statements of commitment to meaningful disclosure, such as CMA's Responsible Care Program. This would lead one to expect that reasonable requests by the Agency to minimize unnecessary CBI claims are likely to be given serious consideration. If such public commitments could be obtained from industry, there are strong incentives for the regulated community to abide by them.

Experience to date indicates that, to be most effective, such "jawboning" efforts would need to be conducted at a high level. Like the aforementioned programs seeking voluntary actions by industry, efforts to obtain voluntary reductions in CBI claims should probably be well publicized by the Agency and cooperating industries. An open question is whether incentives for industry cooperation, such as the incentive to reduce emissions provided by the public dissemination of TRI emissions data, exist for excessive CBI claims.

Get Tough on Egregious Cases

As noted above, the federal government has statutory authority to seek either civil or criminal penalties against persons who knowingly submit false information. EPA has never yet sought any penalties for the submission of invalid CBI claims, no matter how egregiously inappropriate. Selective prosecutions, well publicized, could increase the perceived costs of submitting invalid CBI claims. This approach could also be used to "backstop" other initiatives to induce more appropriate CBI claim behavior. As a tool to facilitate this process, EPA could require CBI claimants to sign certification statements regarding the accuracy of information submitted in support of CBI claims.

This approach does not address legitimate disagreements, such as a situation in which the statements made in support of the claim are true, and yet the claim is not valid under the statute (*e.g.* disagreements over whether or not a given data set represents a health and safety study). Addressing these situations requires EPA to provide clearer specifications of legitimate and invalid claims. Also,

Authorize Sharing of TSCA CBI with State Governments

The current statutory language of TSCA clearly does not provide for the sharing of CBI with officials of state governments, but only with other federal officials. A modification of TSCA to permit such sharing would address the needs of one critical group of potential users of TSCA data for whom access is currently precluded. Providing state government officials with access to TSCA CBI would presumably enable them to act to control potential risks from chemicals subject to TSCA reporting, using their authorities under state law. This would provide the public with another line of defense against such risks. As state officials are fully as capable as EPA of protecting trade secret information, no threat to the security of legitimately confidential information would arise. In itself, this modification of TSCA would not do anything to reduce excessive CBI claims, but could mitigate their impacts. The experiences reported above regarding current data sharing between EPA and other federal agencies suggest that, in order to be effective, procedures for data sharing should incorporate routine notification of both state and federal officials that EPA is in possession of potentially relevant data.

Establish Additional Guidance

EPA would be helped by as much Congressional guidance or specification as possible of the types of information that could, and could not, legitimately be claimed as CBI in submissions under TSCA. Congress could also, independently, provide further specifications to EPA of the conditions under which a potentially valid claim would, or would not, be acceptable. For example, Congress could explicitly incorporate "sunset" provisions on CBI claims, or specify routine periods for re-substantiation of claims. Alternatively, the language of Section 14(b) could be amended to make it absolutely explicit that CBI claims could not be asserted on chemical identity in such submissions. Such specific statutory language would preclude possibly extended rulemaking procedures and judicial confrontations over class determinations proposed by EPA.

EPA Options Whether or Not Congress Acts

EPA does have alternatives available to it to limit inappropriate CBI claims, which would supplement Congressional action. These actions by EPA would also have some salutary effects even in the absence of Congressional action.

Class Determinations

Whether or not there is any change in statutory authority, EPA would be wise to clearly specify those classes of information that it believes do not meet current TSCA criteria for confidentiality. For example, as noted above, OPPT legal analysts have determined that much of the information received by EPA is subject to the strict limitations on CBI claims enumerated by Section 14(b) of TSCA. The Agency could either endorse or reject this analysis.

If it so decided, EPA could simply put submitters on notice (perhaps via the *Federal Register*) that henceforth it would be employing the broad definition of health and safety studies specified in the law and regulations, and restricting CBI claims on those studies to the specific types of information permitted under the statutory language of Section 14(b). This would eliminate a substantial fraction of the claims documented in preceding sections of this report. OPPT attorneys have pointed out that the decision in *Teich vs. FDA* is supportive of this sort of action by a regulatory agency.

establish such a requirement would require EPA to go through a difficult, potentially time consuming, and uncertain rulemaking process.

Moreover, this policy would only be effective to the extent that EPA could muster the staff resources to review a meaningful set of substantiation documents. As OPPT staff have noted, challenging a claim is a labor-intensive process. Submitters can be expected to provide meaningful substantiation of their CBI claims only to the extent that there is a realistic expectation that their substantiation materials will be reviewed. It may or may not be possible to implement a selective, yet unpredictable, review process, in a manner analogous to IRS audits.

Sunsets/Resubstantiation

There was a widespread consensus among persons contacted in this study that many data elements for which a valid CBI claim had been asserted would not require CBI protection at some later date. There was far less consensus regarding the feasibility of developing a workable "sunset" provision for such claims. This approach provides the benefit of the doubt for submissions where there is a *prima facie* case that CBI protection is warranted (*e.g.* on new chemicals not yet marketed), and is explicitly supported by Executive Order 12600 (June 23, 1987), for information submitted after January 1, 1988. A key advantage of this approach, if it can be made to apply to earlier submissions, is that it would *automatically* eliminate EPA's CBI backlog, unlike many other alternatives. However, requirements to provide individual notice prior to revealing material claimed as CBI make it difficult to institute sunset provisions without statutory change.

EPA might have better success with periodic re-substantiation, which allows submitters to maintain CBI claims as needed, but drops protection for those that are no longer substantiated. EPA's Office of General Counsel has determined that whenever a business has failed to furnish comments in response to a request for substantiation by the specified due date, the information covered by the CBI claim can be made public by OPPT without any further notice to the submitter or approval by OGC (Class Determination 1-85). This would appear to provide the necessary basis for a comparatively automatic declassification system. As in the case of pesticide re-registrations under FIFRA, submitters would have to make a positive effort (if only the submission of routine substantiation materials) to maintain their CBI claims. This is a relatively small cost to maintain these claims.

Fees on CBI Claims Based on Class Determinations

Fees for TSCA CBI claims represent another mechanism to discourage unnecessary claims by imposing costs on the submitter. In this case, the costs imposed would be direct, rather than in terms of increased effort or risk of penalty. The particular fee imposed could be selected to reflect EPA's degree of interest in public dissemination of the data, or the strength of the statutory prejudice against a particular class of claim.

This is one of the simplest mechanisms for imposing costs for frivolous submissions, and may motivate the review of CBI claims by corporate management (much as the economic losses represented by TRI emissions seem to have lead to a de-compartmentalization of corporate evaluations). If treated as a special "user fee," which seems entirely reasonable, this could also help to provide OPPT with the resources needed to review CBI claims and safeguard legitimate CBI. EPA's success in instituting a PMN processing fee seems to offer promise that this could be implemented without excessive difficulty. Open issues involve the question of whether a fee structure could be devised that is both effective and considered reasonable by submitters.

adding a certification statement section to reporting forms will involve a possibly extensive review process.

Eliminate Overly Burdensome Administration of CBI

As noted above, OPPT is already taking steps to decrease the administrative burdens imposed on it by CBI requirements. Many of these address internal EPA costs, but would not provide for greater access to data outside of OPPT. One avenue to approach would be memoranda of understanding with other federal agencies to facilitate data sharing.

EPA Options If Congress Does Not Act

If Congress does not amend TSCA, there are additional actions that EPA could take to further discourage invalid CBI claims. Most of these would be superseded by the statutory changes discussed above.

Report Cards

One suggestion for increasing the incentives for submitters to assert as few CBI claims as possible is for EPA to publish a "report card" indicating for each submitter the number of submissions, the number of CBI claims, and perhaps the number of challenges issued on these claims. The idea is that companies making few claims would be rewarded by public acknowledgement of their openness, and public pressure would incline submitters to reveal as much information as possible. This reasoning anticipates effects that parallel those that have been observed in chemical industry behavior as a consequence of the public release of TRI data. It is not clear that this represents a strong incentive.

Reporting of Aggregates and Generic Data

As noted above, when specific information is claimed as CBI, it is often possible to obtain generic information regarding the same data elements. The quality of such generic information obtained thus far has been called into question (see Appendix B). EPA could further strengthen such generic reporting be analyzing its databases and reporting aggregated data in a form that would obscure specific CBI data elements. Such an approach does not rely on any changes in submitter behavior, but is entirely within EPA control. However, it has been forcefully argued that generic information is inadequate for many purposes, and some have questioned the ability of data aggregation techniques to adequately protect CBI when only a limited number of submissions have been received.

"Up-front" Substantiation

While both statutory and regulatory language appear to place the burden of substantiating CBI claims on the submitter, the onus is on EPA to challenge claims and/or demand substantiation. Under most of the reporting provisions of TSCA, EPA has not asked companies to substantiate CBI claims upon submission. Thus, companies have been free to make broad claims, and EPA has had to employ a post-facto challenge process, as with 8(d) and 8(e) submissions. The one exception was for new chemical Premanufacture Notifications under the interim reporting requirements in effect until 1983. After the removal of this requirement, the amount of CBI submissions increased significantly. Experience with EPCRA also suggests that up-front substantiation requirements can reduce confidentiality claims. To re-

All available administrative options to discourage the assertion of invalid CBI claims are likely to impose significant costs on OPPT, at least in the short term. Any change from current policies, even those that require no change from published regulations, seems likely to encounter inertia, if not hostility, on the part of submitters. The current policy of leniency regarding CBI claims, notwithstanding fairly strict regulatory language, appears to have been in effect almost from TSCA's inception. Thus, no change in policy seems likely to succeed unless it is accompanied by a corresponding effort to review and challenge CBI claims. Once submitters become accustomed to revised procedures, it may be possible to reduce the resources allocated to challenging invalid claims.

A first priority would appear to be the need to clarify the implementation of Section 14(b) of TSCA, through the explicit specification of guidelines (and perhaps clarification of regulatory or statutory language) regarding information that the Agency will treat as a health and safety study subject to that section. Because much of the data of greatest potential use outside the Agency represent submissions that appear to fall under this section, strict enforcement of the limitations on CBI claims under Section 14(b) might eliminate a significant number of negative consequences of invalid claims. A firm stand on these statutory limitations to CBI claims would appear to offer greater promise than more general attempts to impose costs for submitting invalid claims. This option may or may not require formal rulemaking; an explicit statutory clarification could greatly facilitate this revision. If necessitated by continuing submissions of large numbers of excluded claims, this policy could be backed by penalty provisions (which appear to require the promulgation of new rule(s)).

EPA appears to have numerous options to discourage invalid or frivolous CBI claims in the future. While some of these require neither regulatory nor legislative action, all entail significant expenditure of resources. Reducing the flow of invalid CBI claims will not, however, address the problem of claims submitted in the past. Data have been accumulating in EPA files for more than a decade. In order to address these data, EPA faces a truly massive commitment of effort to review and challenge activities. It may lack the resources to make such a commitment. The declassification of these data might be more effectively pursued through explicit legislative language in a reauthorization of TSCA.

CONCLUSIONS

A vast amount of information has been submitted to EPA under TSCA since the compilation of the original TSCA Inventory. A significant fraction of this information (50 percent or more) has been subject to CBI claims. The proportion of data submitted under TSCA that is covered by CBI claims is much greater than that for data submitted under other statutes that collect comparable information, but impose more stringent requirements for asserting confidentiality claims.

While it is impossible to establish the validity of any individual CBI claim without examining the materials provided to substantiate that claim, all available evidence supports the proposition that much of the information covered by CBI claims is not legitimately entitled to protection as TSCA CBI.

- For those cases in which a direct comparison can be made to substantially identical information reported under TSCA and under EPCRA, the CBI claim rate under TSCA is *at least* 10 times higher than the rate of trade secret claims under EPCRA; more probably, the claim rate is more than a thousand times higher under TSCA.

- In those cases where EPA has had the resources to evaluate individual CBI claims, it has determined that a significant fraction of the submissions (up to 50 percent or more of Section 8(e) filings) contained invalid CBI claims. When submitters of these claims were challenged, EPA prevailed *in every case.*

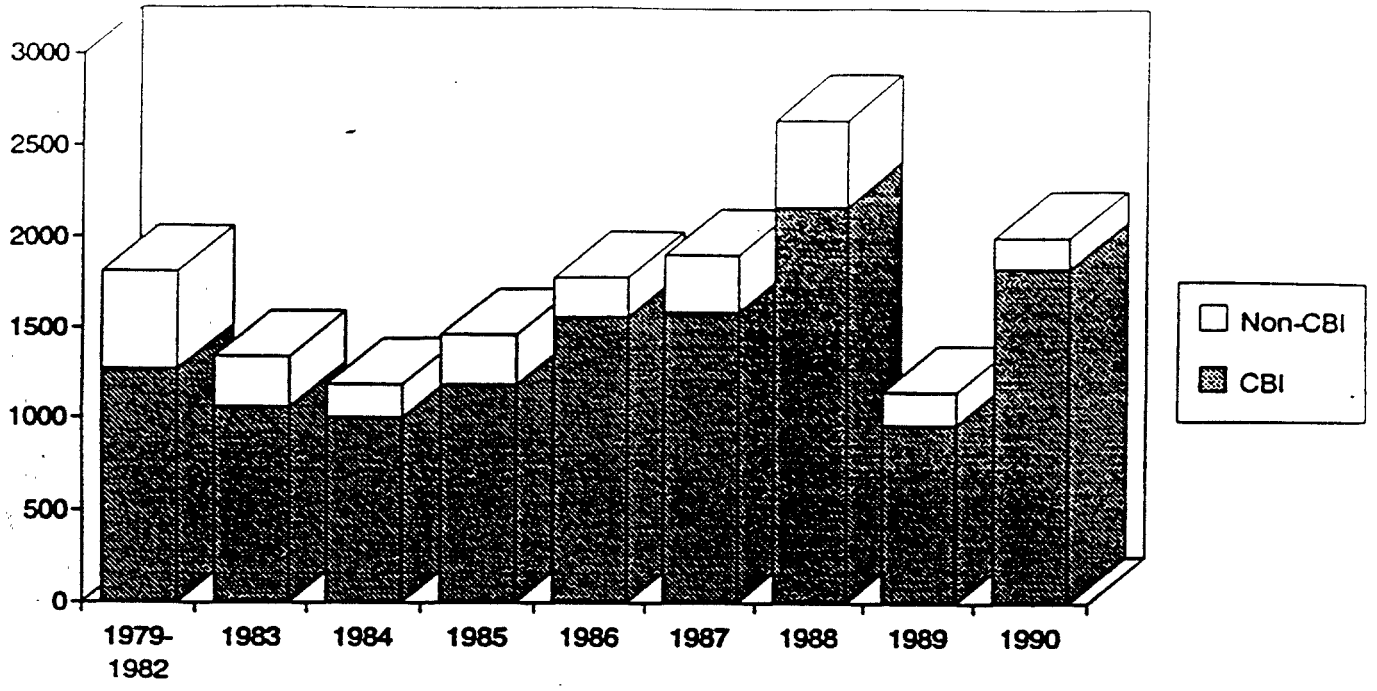
- Legal analyses by OPPT attorneys indicate that EPA has historically accepted CBI claims on data elements that *are not entitled to protection* as CBI under the statutory language of Section 14(b) of TSCA. Existing regulatory language, as well as the statute and the legislative history, supports this analysis.

Under existing procedures, EPA has no effective control on invalid or even frivolous claims, with the single exception of the recently initiated program to review 8(d) and 8(e) submissions. Currently available staff resources do not permit any significant expansion of this program, and anticipated increases in 8(e) submissions may exceed available resources. EPA practices for safeguarding CBI have effectively prevented damage to submitters from disclosure, but EPA appears to be providing protection to a considerable body of data that is not entitled to such protection; thus resources that could be applied to the protection of legitimate trade secret information are presumably being diverted for the protection of frivolous claims. Notification provisions in the statute further complicate the process of disclosing data that have been inappropriately claimed to be CBI. Because EPA's ability to winnow valid CBI claims from frivolous claims, once the claim has been asserted, is limited, EPA may wish to concentrate its resources on devising means of discouraging the submission of invalid CBI claims.

In addition to the costs imposed by invalid CBI claims on OPPT internal functioning, the data covered by invalid CBI claims represent a valuable resource that could further the purposes of TSCA if they could be more widely disseminated. Wider dissemination of this information would fulfill TSCA's intent of allowing the public to make *informed* decisions regarding chemical risks, and allowing market forces to remove unnecessarily risky chemicals from commerce. Public interest groups, other federal agencies, and state governments have all indicated that TSCA data could be very useful in their efforts to protect human health and the environment, if not protected by CBI claims. TSCA data could represent a major information source to improve the scientific foundations of toxicology and risk assessment. Lastly, EPA's own efforts to make its decisions more comprehensible to the public would also be considerably facilitated by the removal of invalid CBI claims that obscure the reasoning underlying Agency actions.

FIGURES

PMN Submissions - Chemical Identity Claimed as CBI



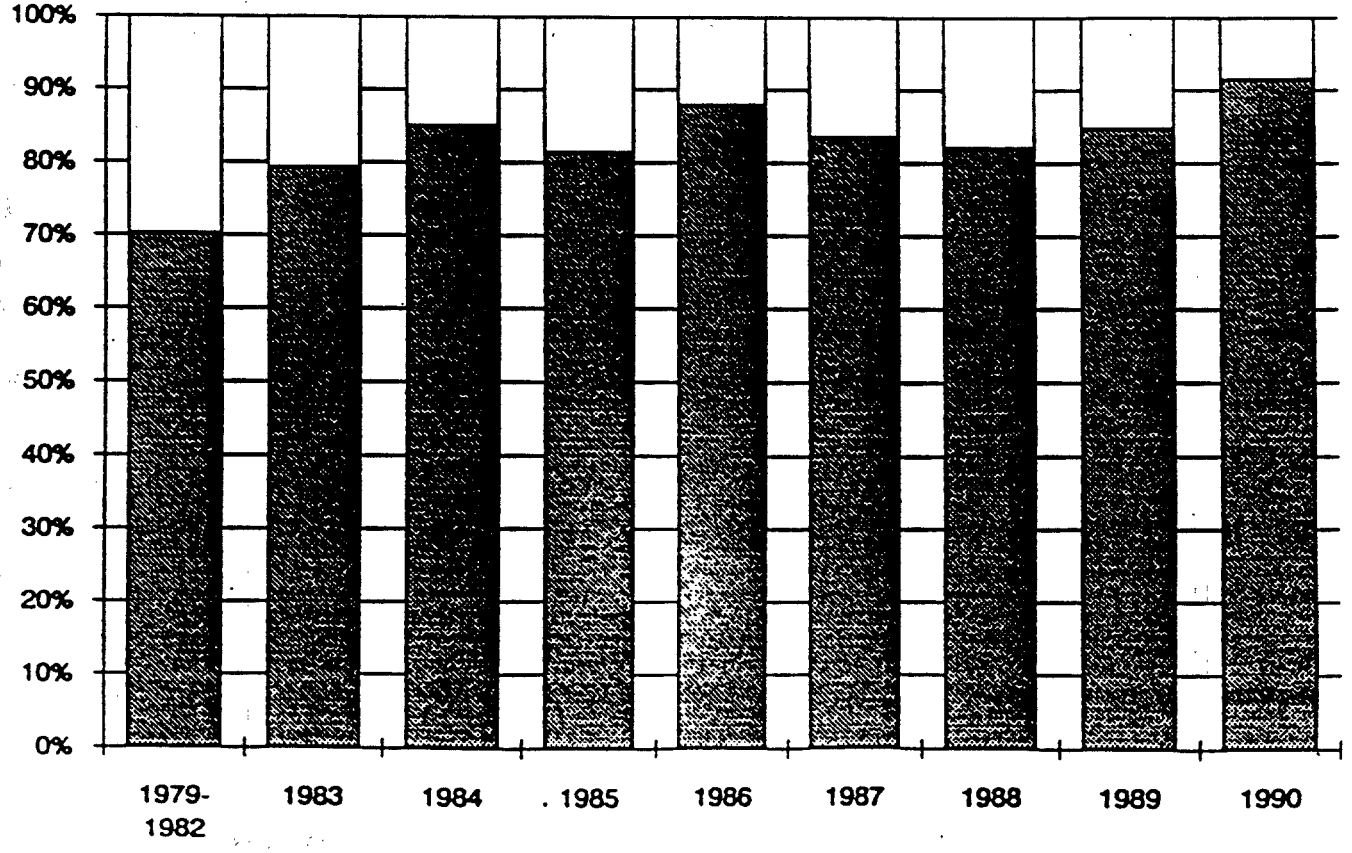
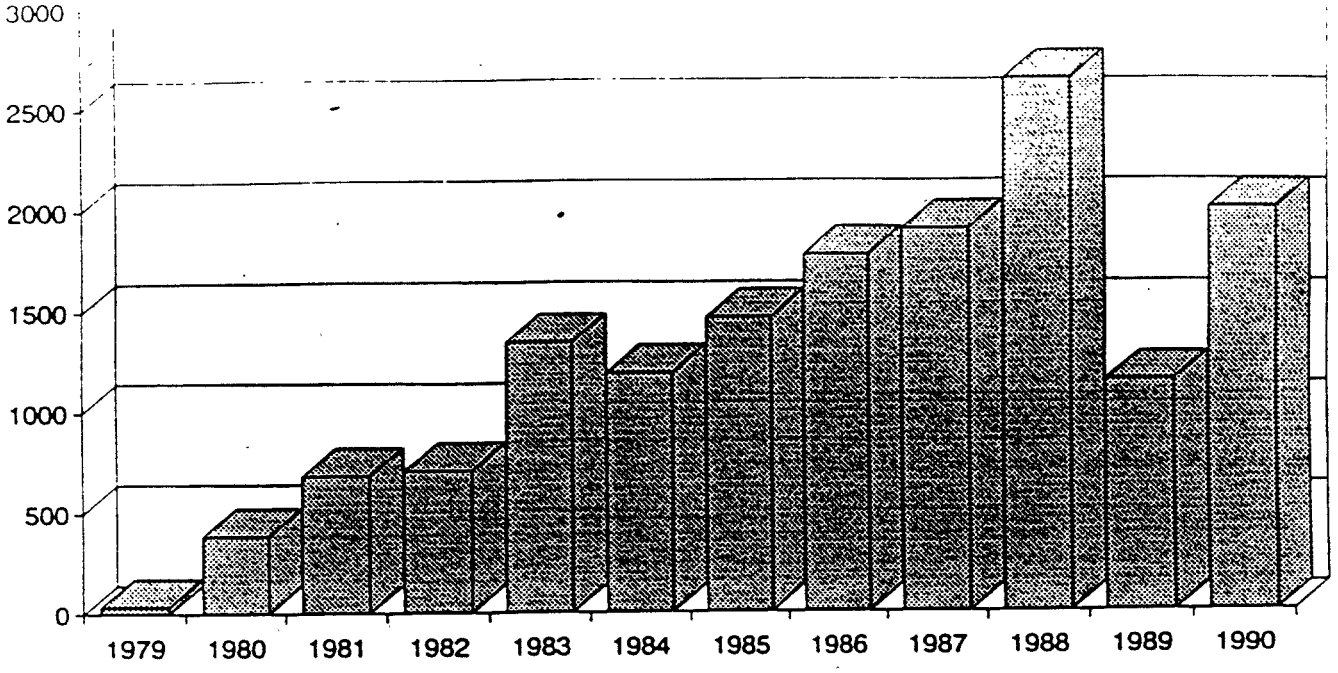
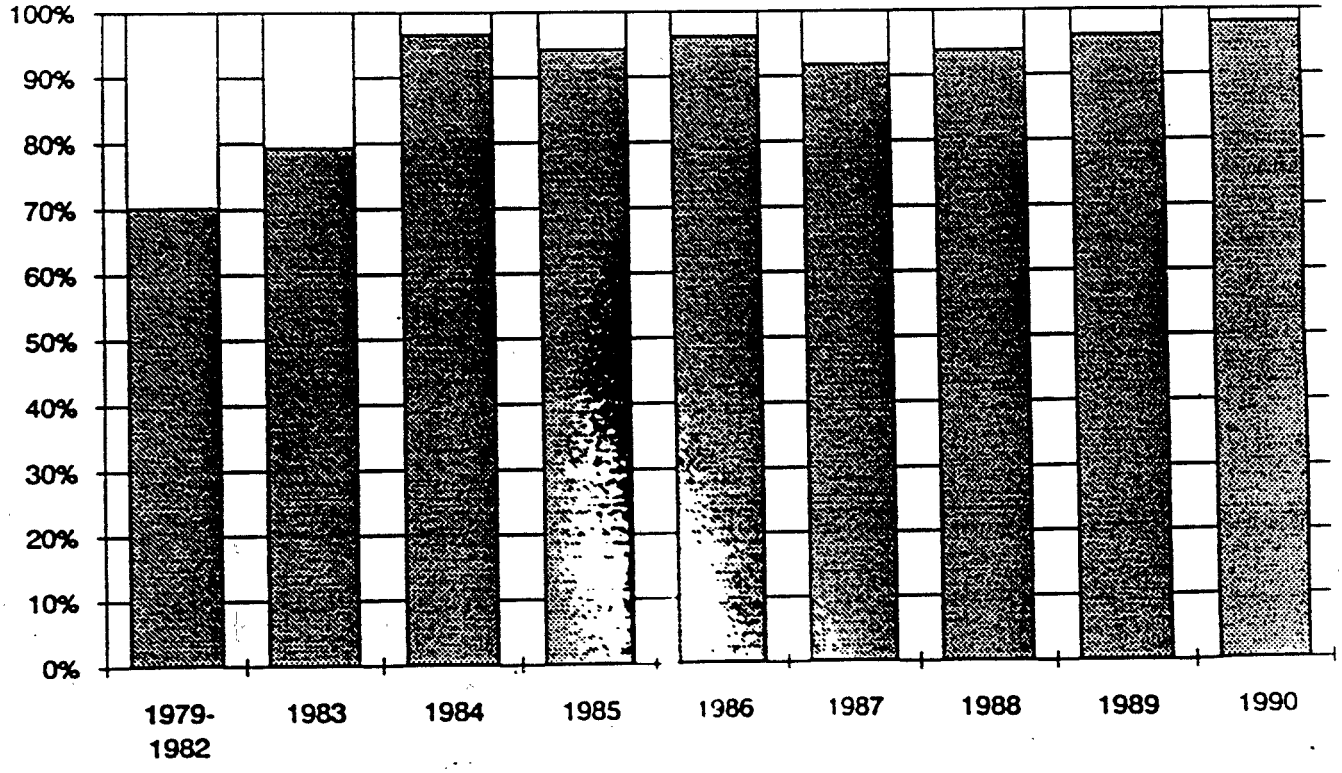


FIGURE 2

C00059

PMN Submissions - Total



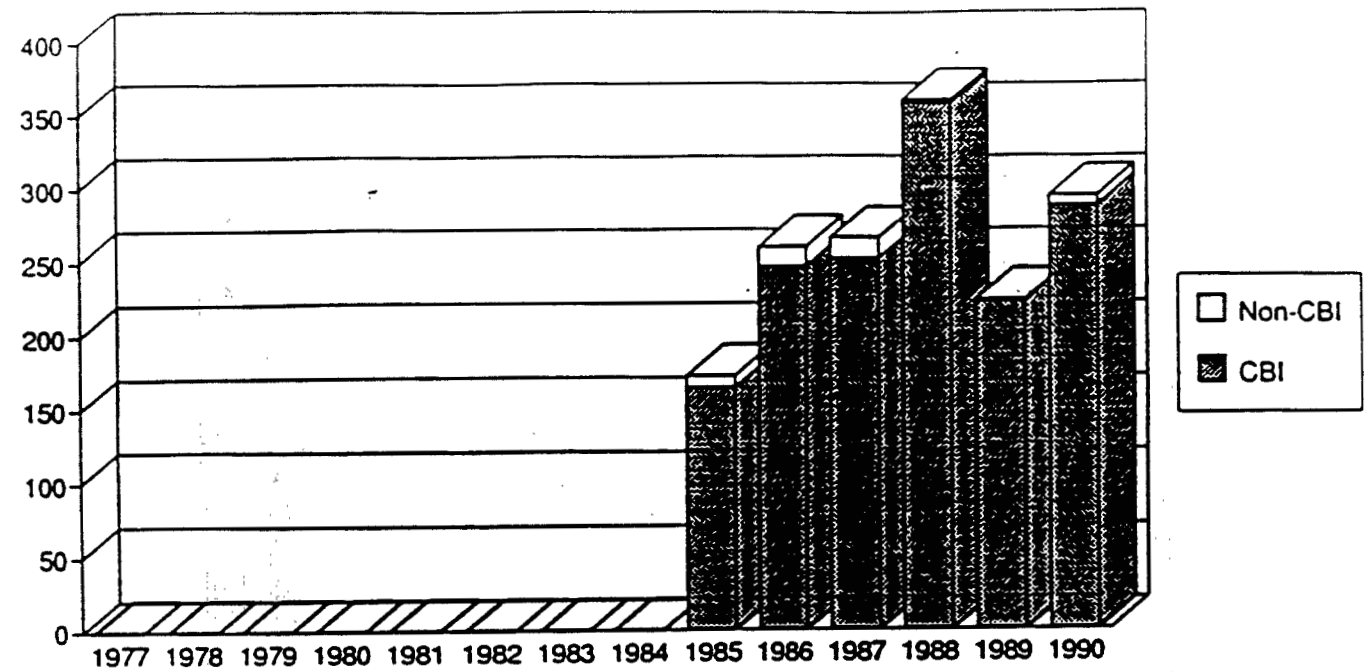


NOTE: For 1979-1982 and 1983, percentages may be imprecise

FIGURE 1

C00058

Polymer Exemption Submissions - Overall CBI Claims



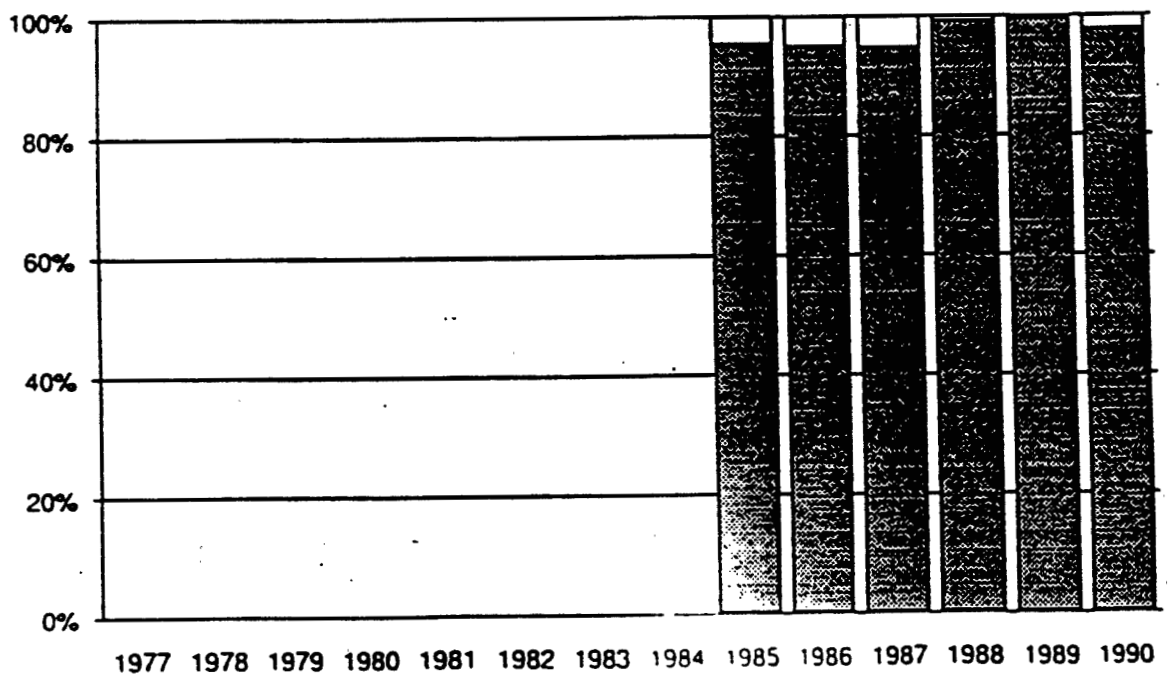
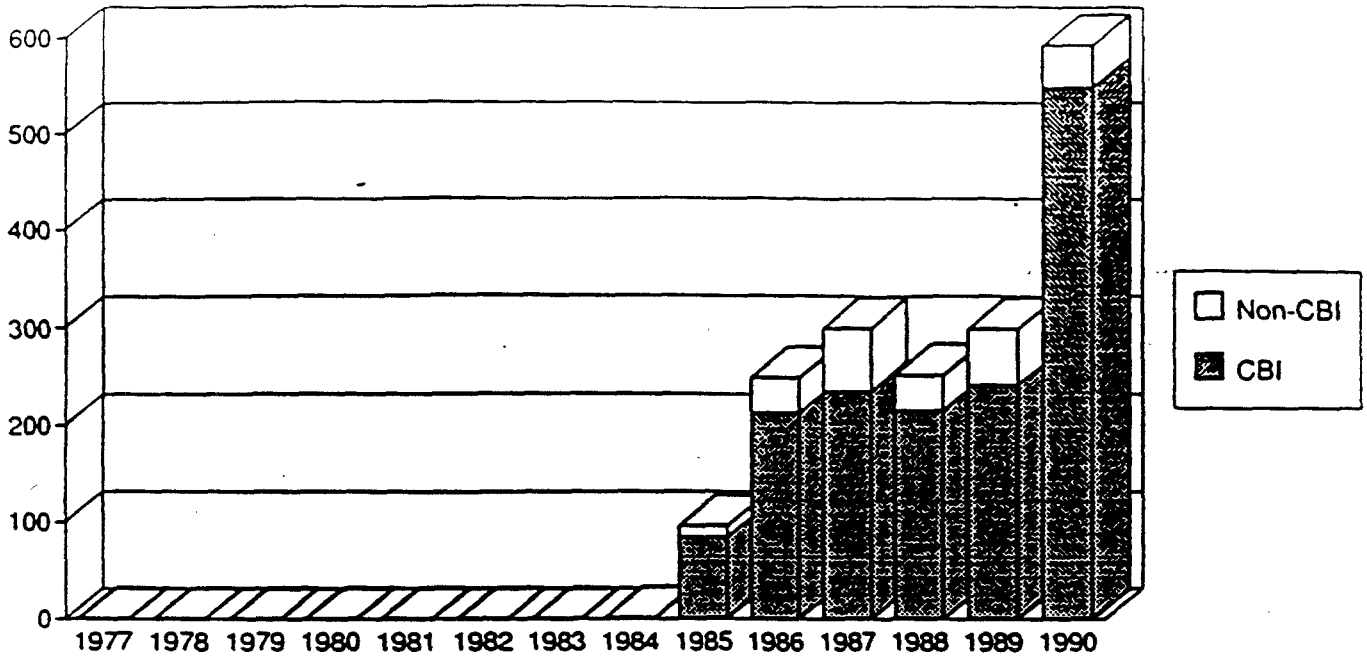


FIGURE 3

Low Volume Exemption Submissions - Overall CBI Claims



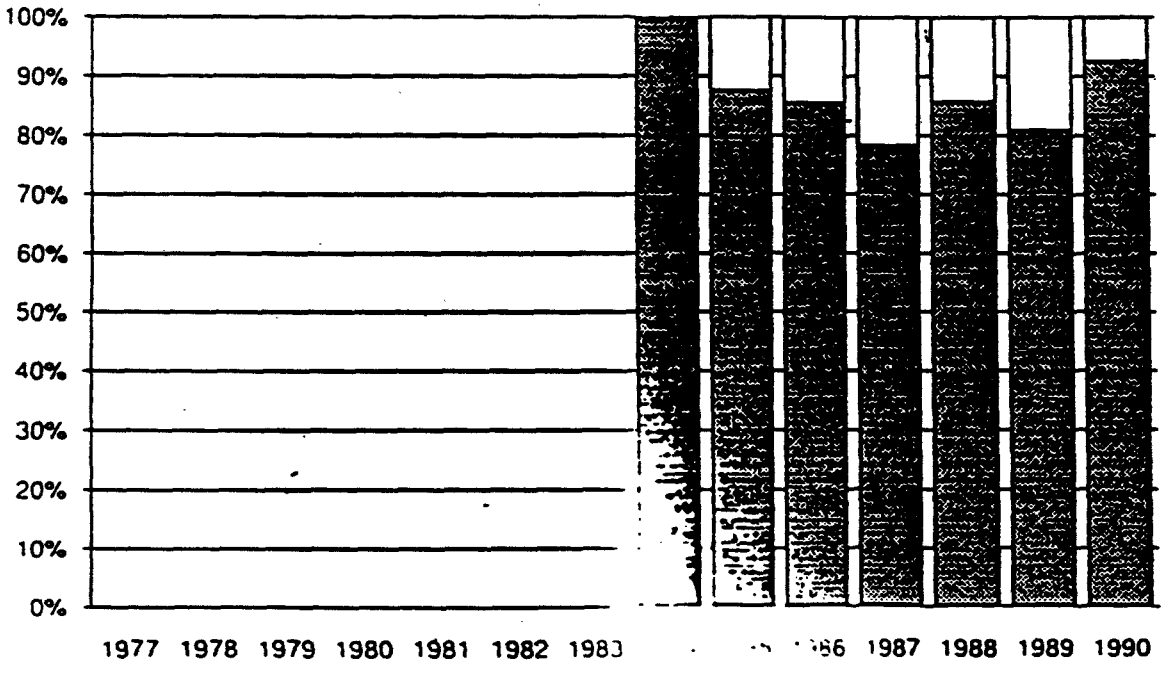
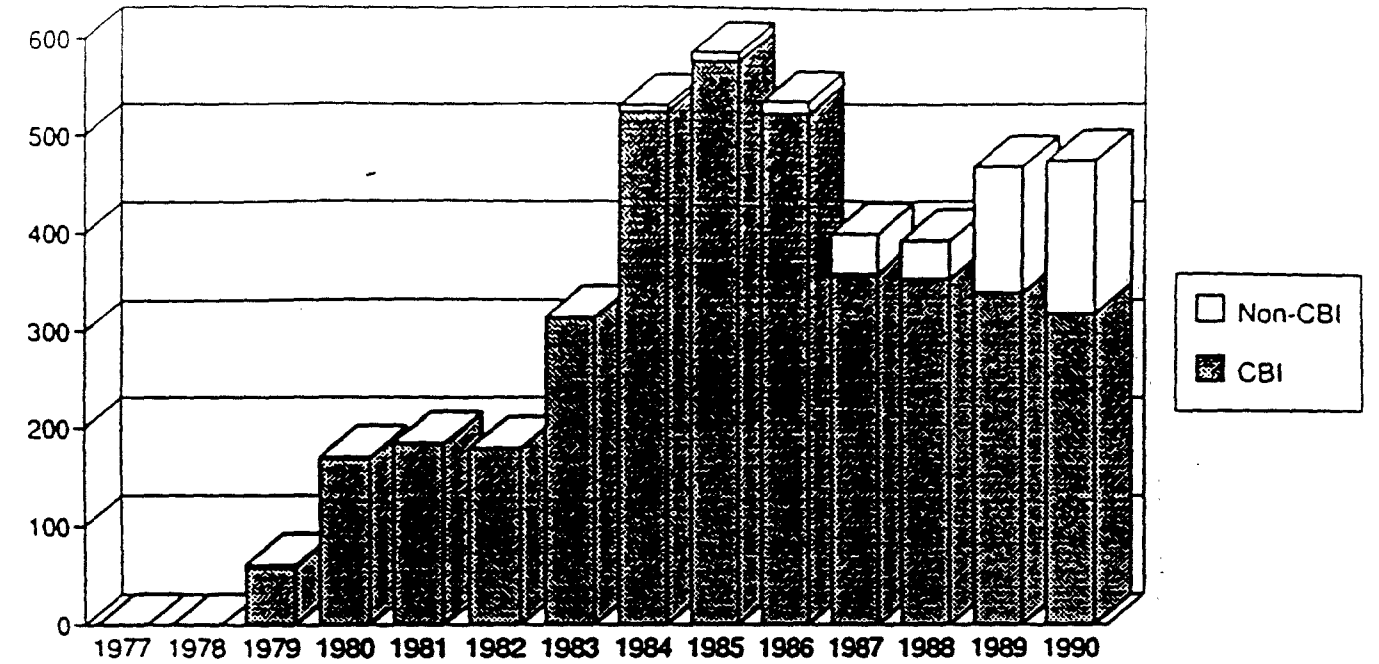


FIGURE 4

Bona Fide Submissions - Overall CBI Claims



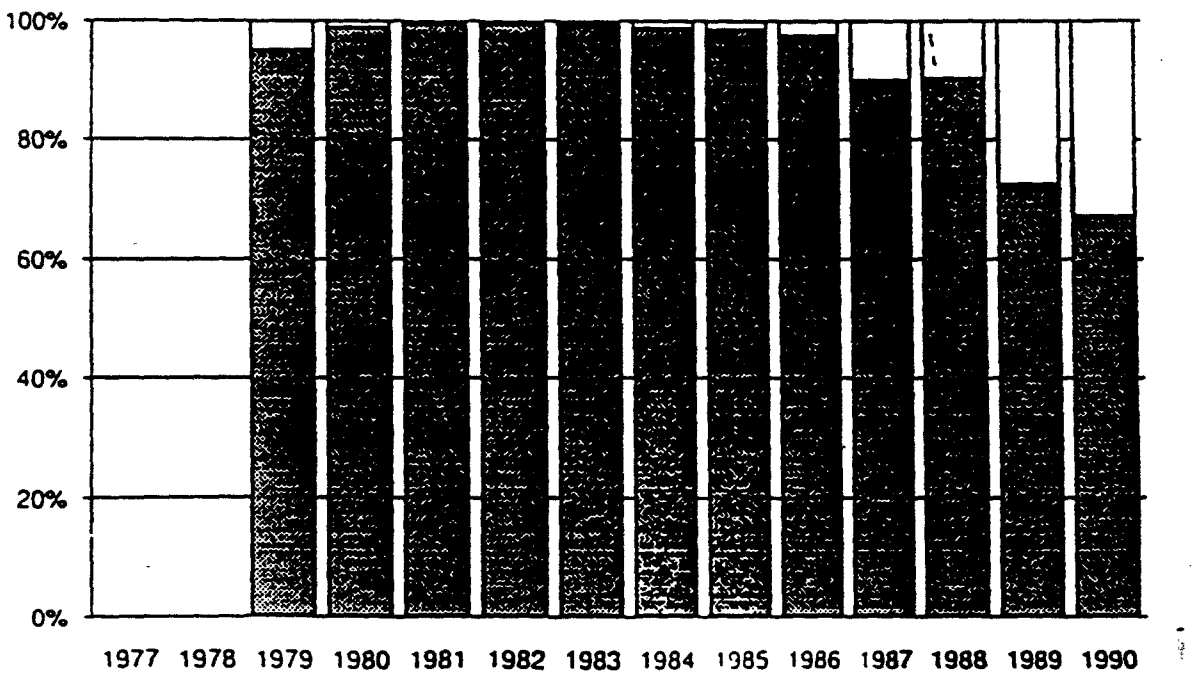
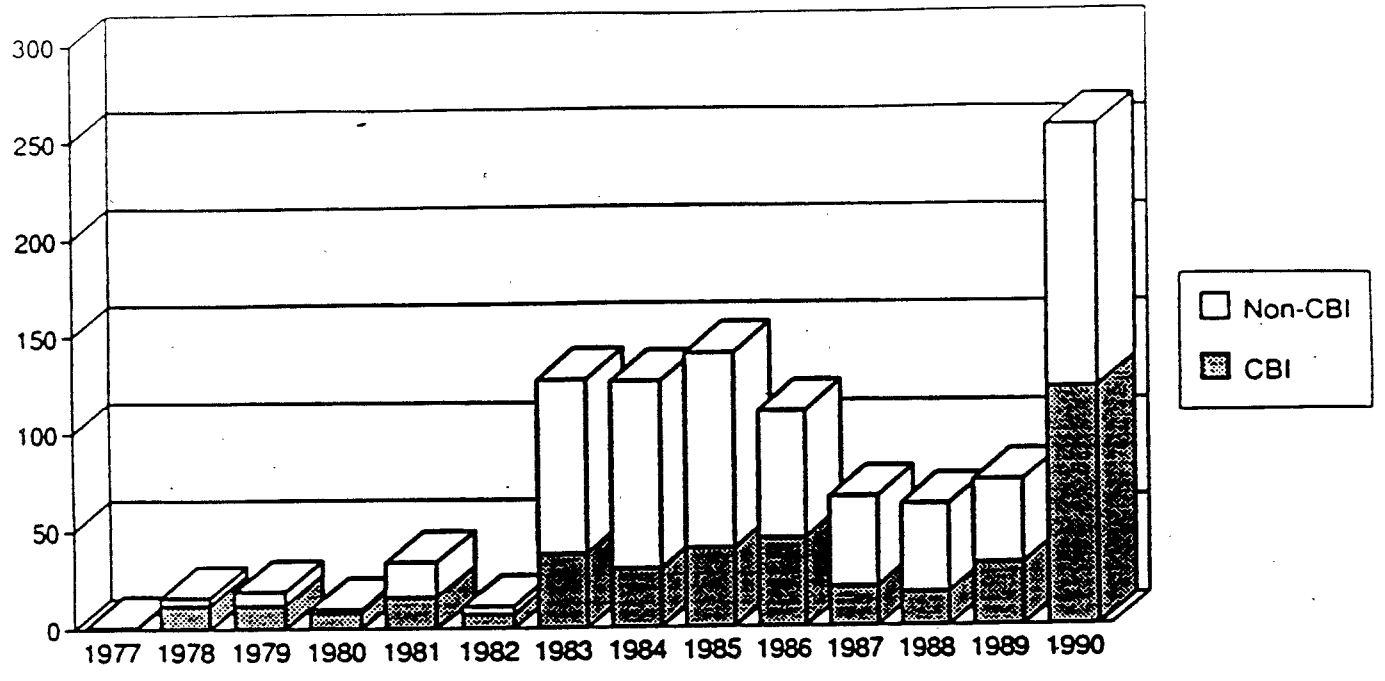


FIGURE 5

8(e) Submissions - Overall CBI Claims



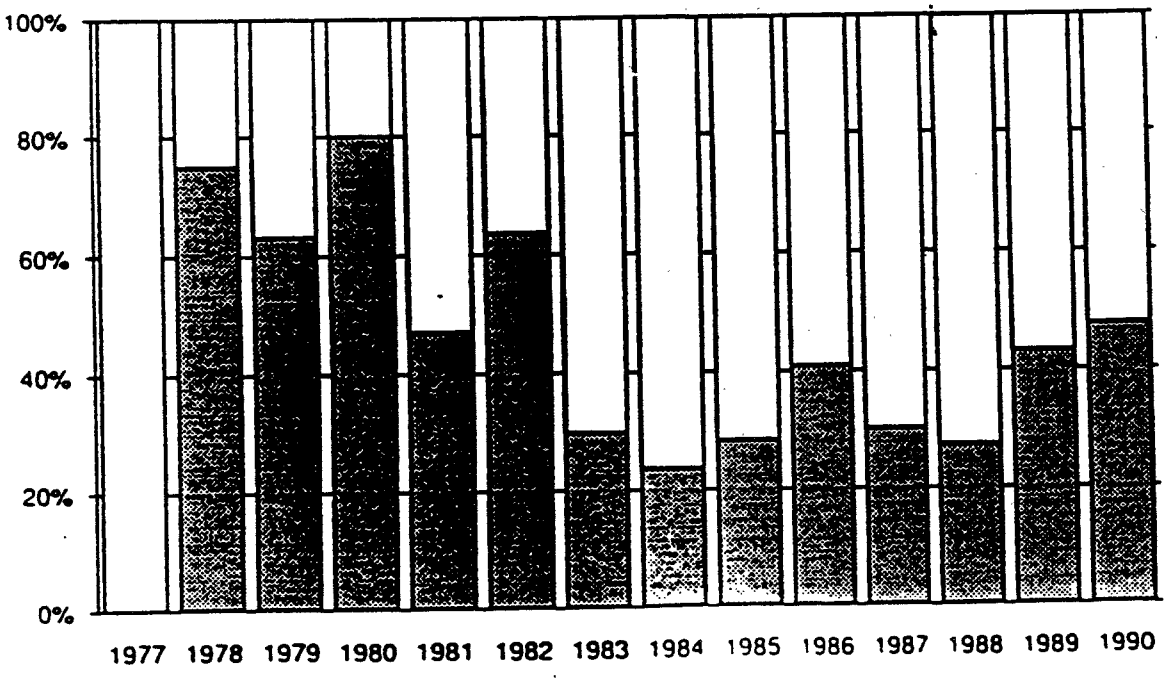


FIGURE 6

8(e) Submissions - Chemical Identity Claimed CBI

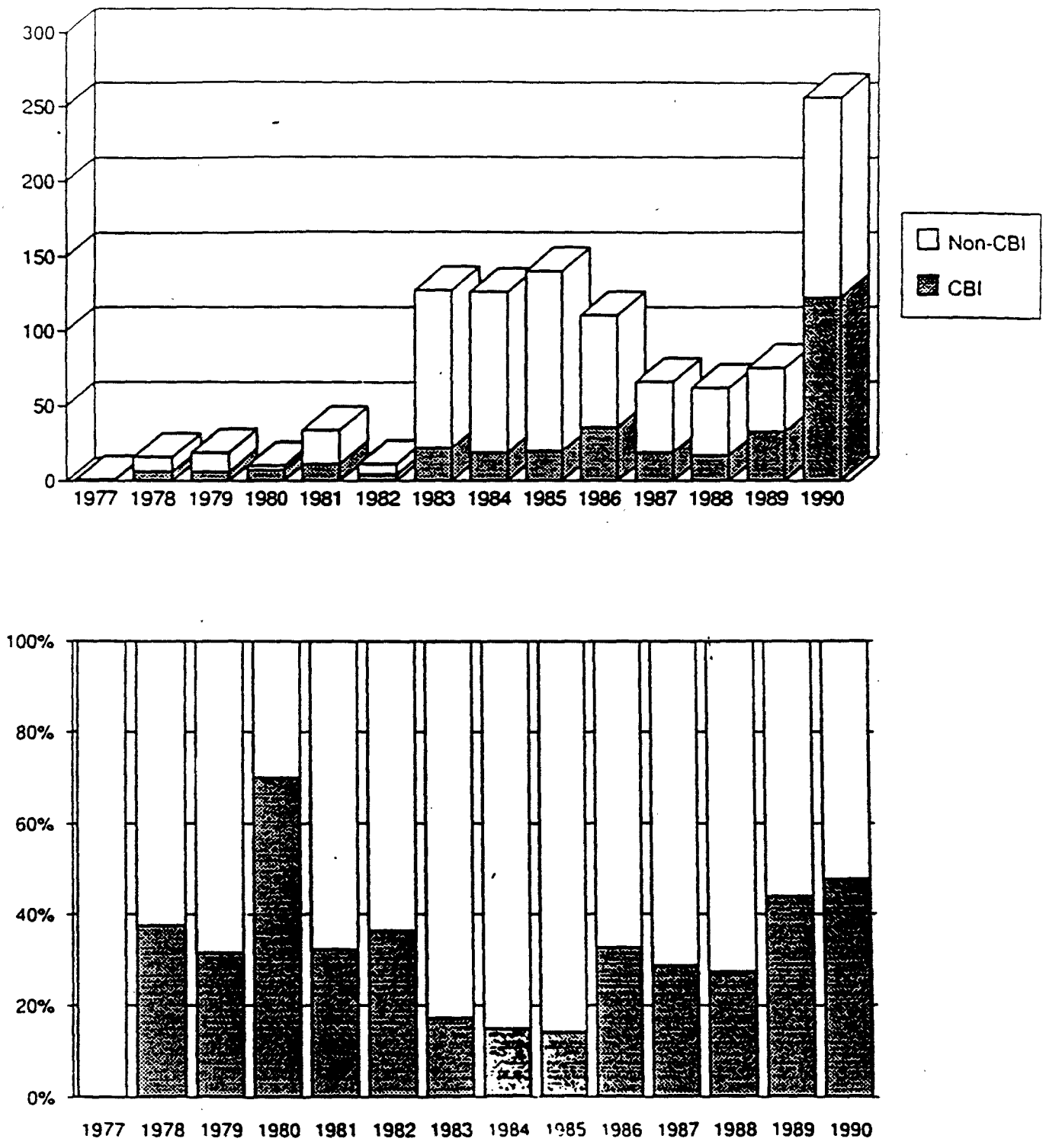
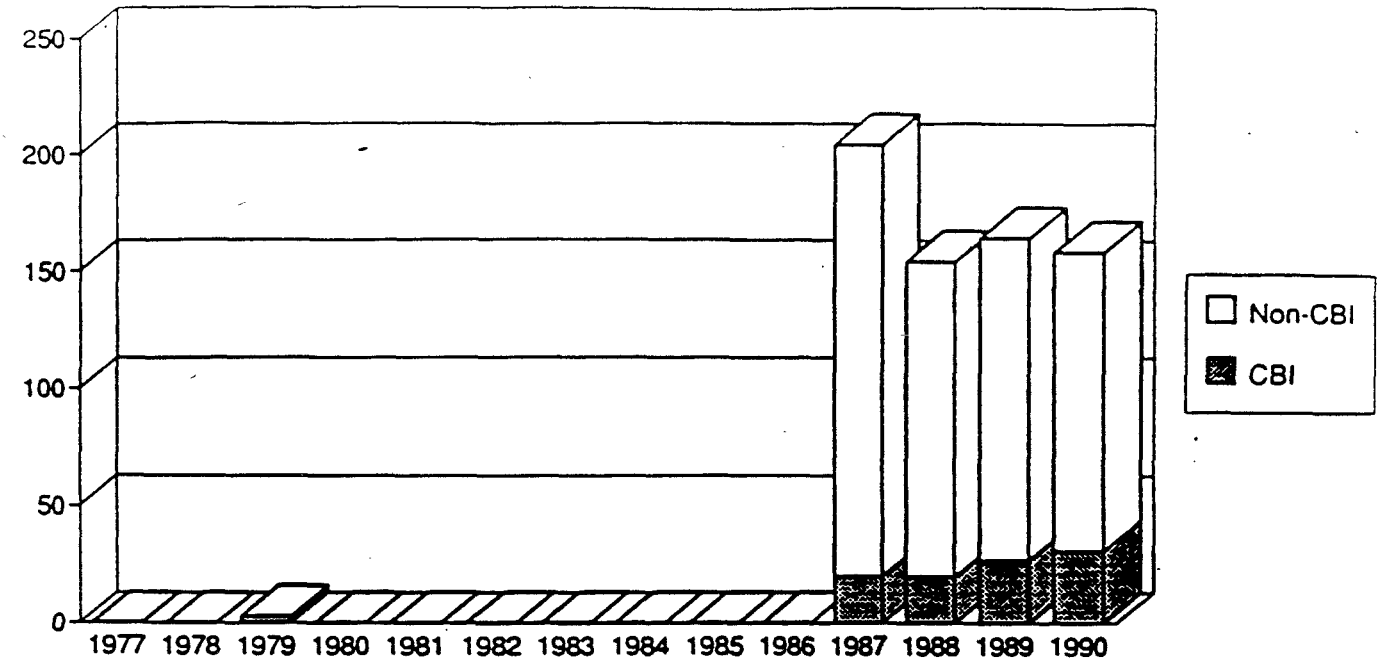


FIGURE 7

FYI Submissions - Overall CBI Claims



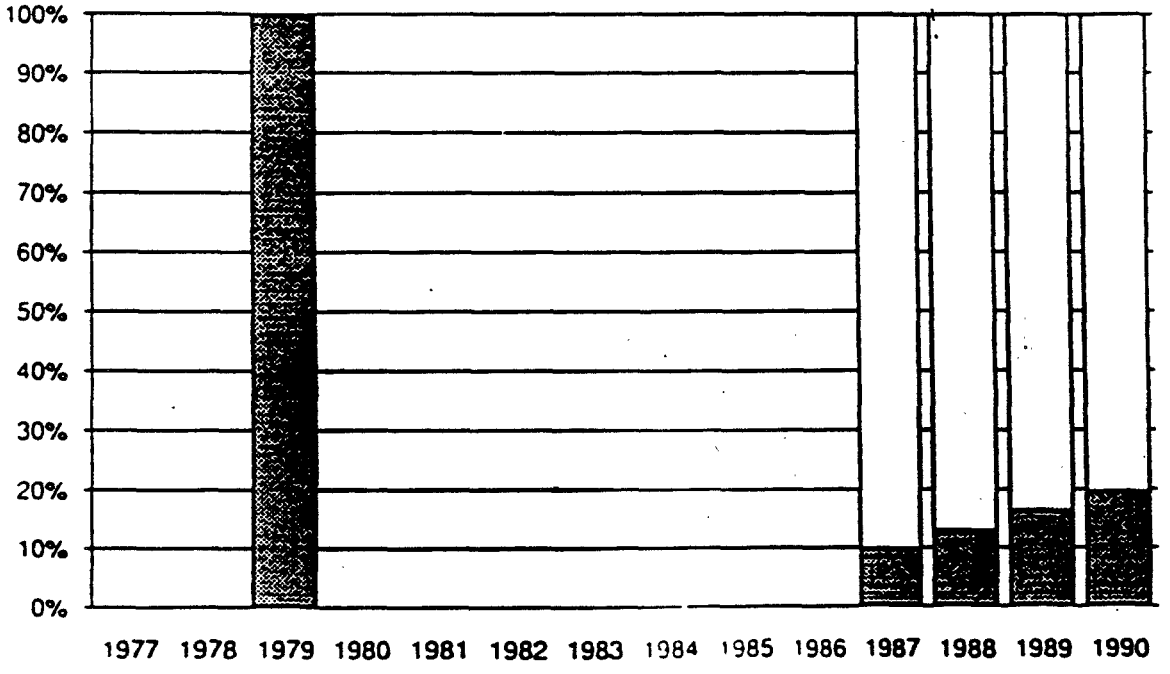


FIGURE 8

Section 8(d) Submissions - Overall CBI Claims

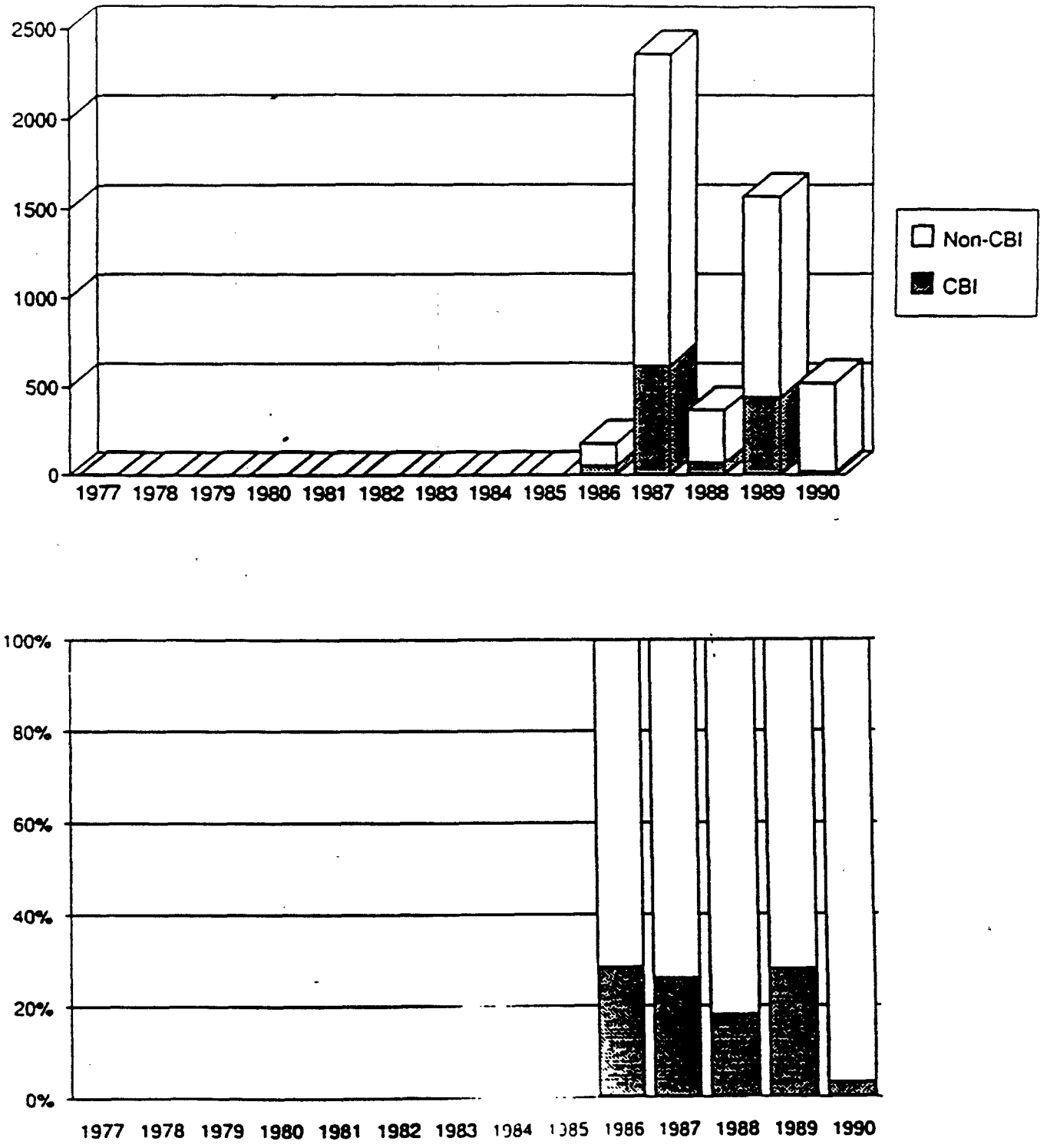
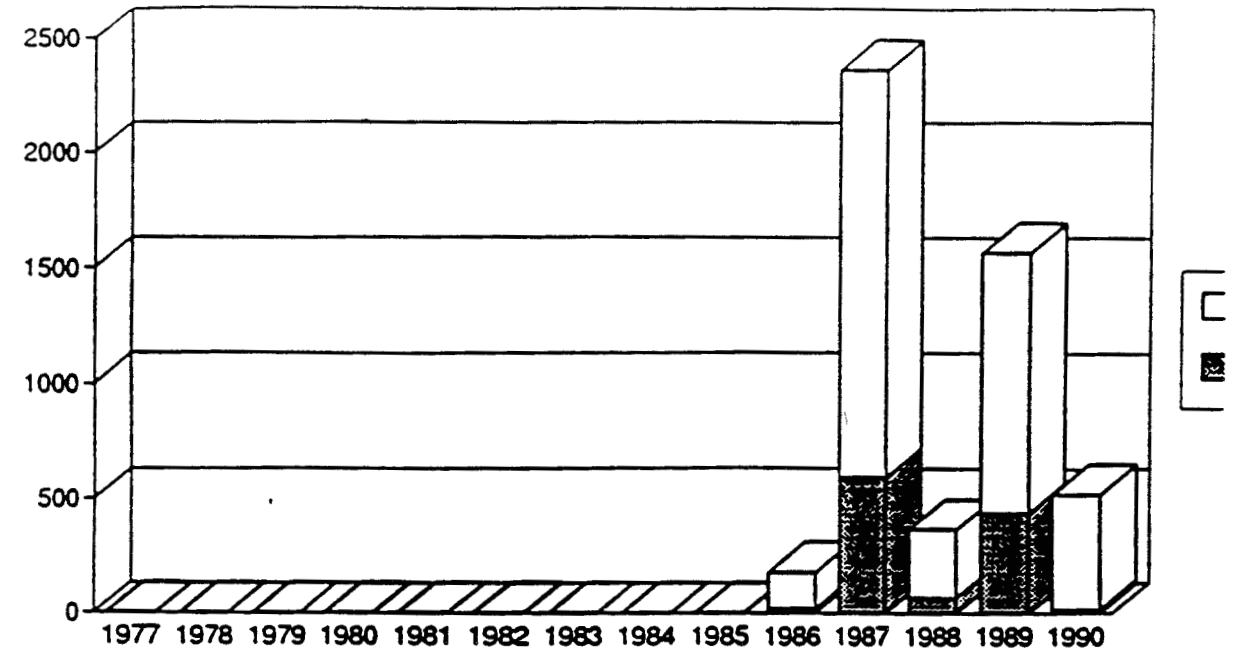


FIGURE 9

Section 8(d) Submissions - Chemical Identity Claimed CBI



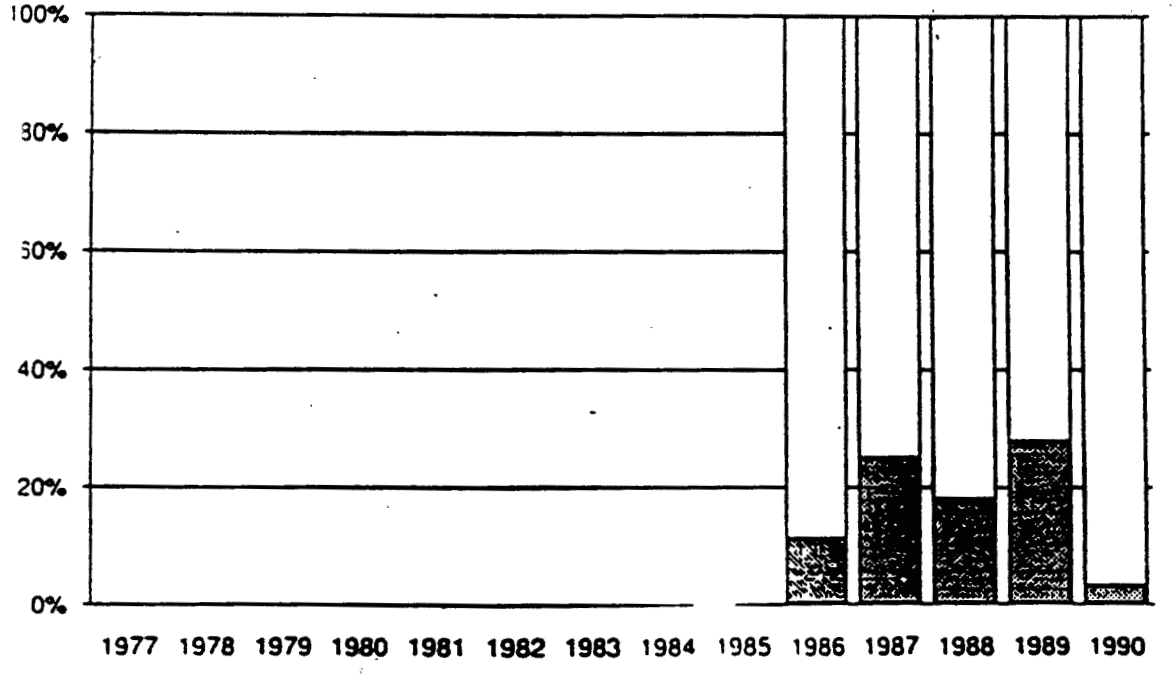


FIGURE 10

Section 4(c) Submissions - Overall CBI Claims

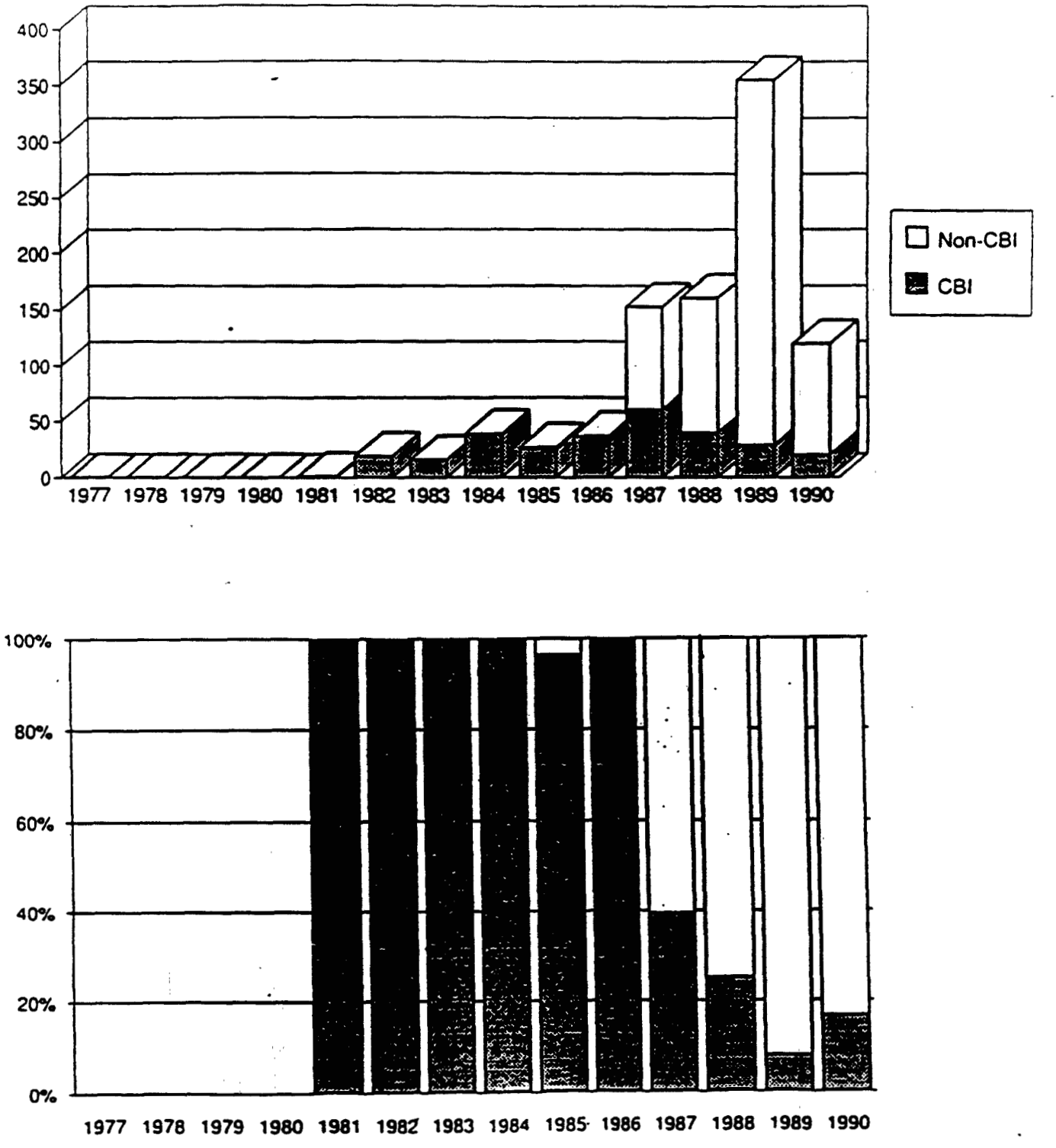
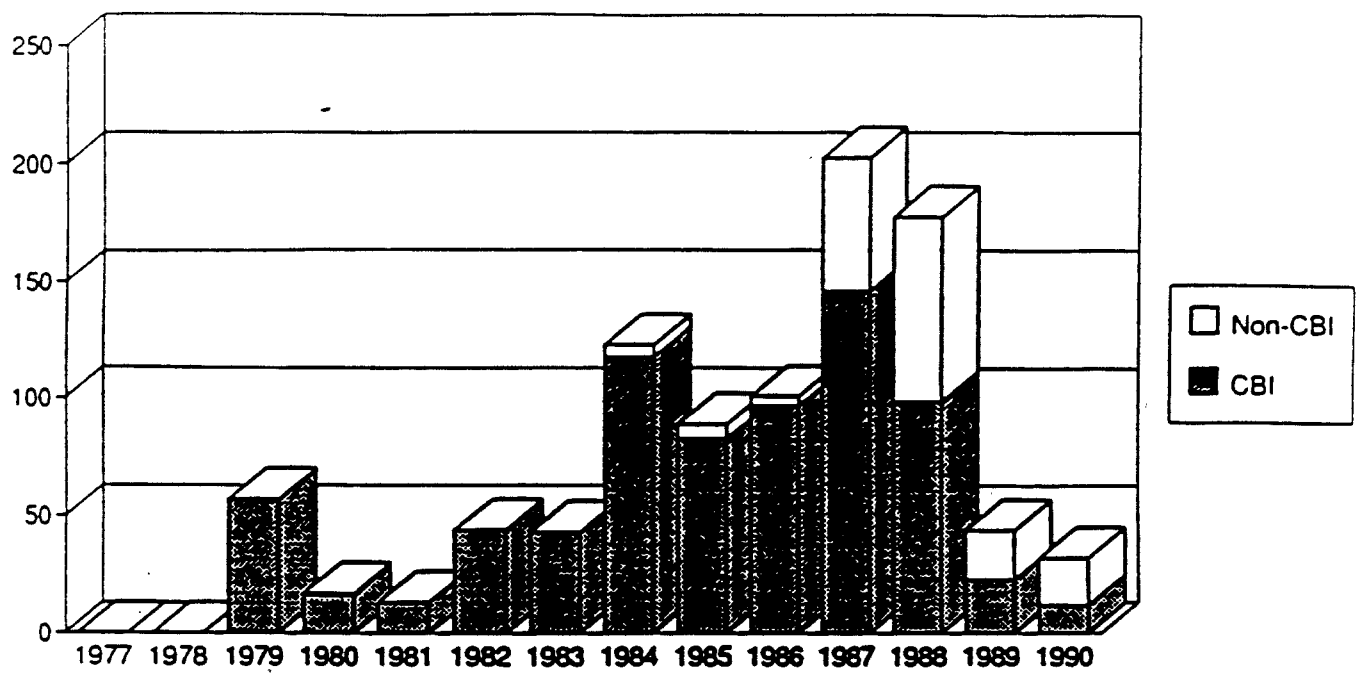


FIGURE 11

Section 6 Submissions - Overall CBI Claims



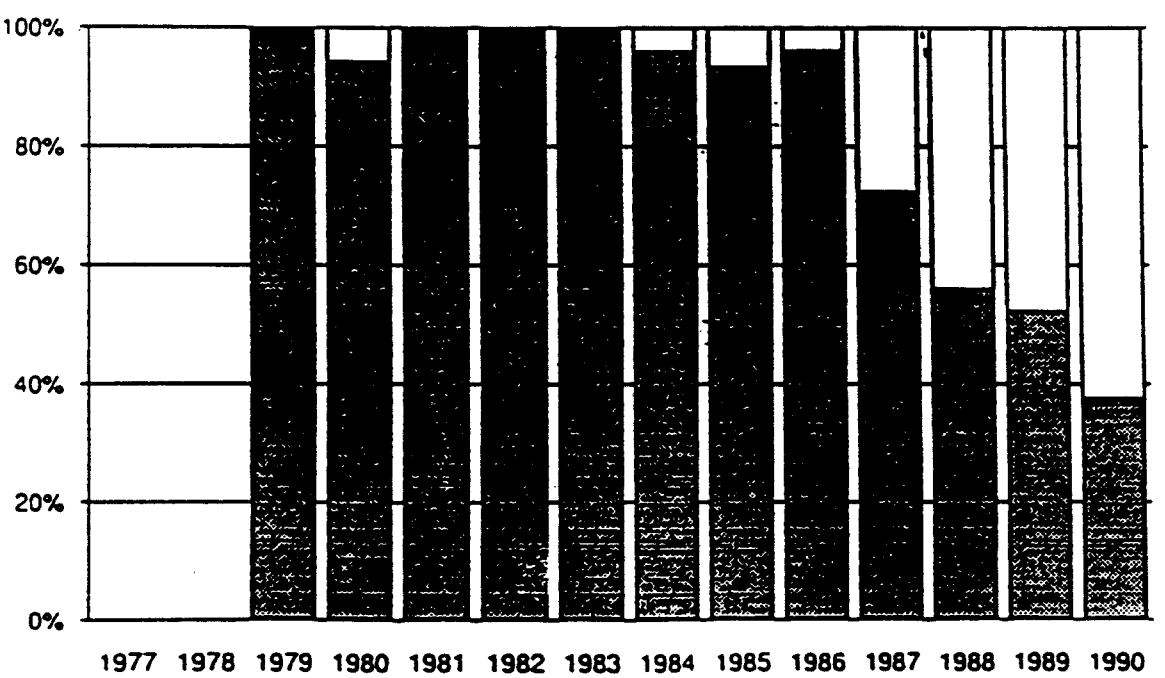


FIGURE 12

TABLES

Table 1

CAS NO.	CHEMICAL NAME	TRI Forms		PAIR Forms		
			Producers		Losses	Percentage
		Total	/ Importers	Total	Claimed CBI	CBI
67-72-1	Hexachloroethane	22	8	5	3	60.00%
71-55-6	1,1,1-Trichloroethane	3,633	17	9	7	77.78%
75-09-2	Dichloromethane	1,567	20	10	6	60.00%
75-21-8	Ethylene oxide	200	16	19	17	89.47%
75-56-9	Propylene oxide	123	7	6	6	100.00%
77-47-4	Hexachlorocyclopentadiene	5	3	2	0	0.00%
77-78-1	Dimethyl sulfate	32	4	2	2	100.00%
78-87-5	1,2-Dichloropropane	12	3	3	3	100.00%
79-00-5	1,1,2-Trichloroethane	29	8	3	0	0.00%
80-62-6	Methyl methacrylate	215	8	5	5	100.00%
84-66-2	Diethyl phthalate	31	4	2	2	100.00%
84-74-2	Dibutyl phthalate	122	8	7	5	71.43%
92-52-4	Biphenyl	174	17	7	4	57.14%
95-50-1	1,2-Dichlorobenzene	45	4	4	4	100.00%
95-80-7	2,4-Diaminotoluene	2	1	4	3	75.00%
96-09-3	Styrene oxide	6	1	1	1	100.00%
98-82-8	Cumene	115	13	15	5	33.33%
98-87-3	Benzal chloride	3	2	1	1	100.00%
98-88-4	Benzoyl chloride	21	3	3	2	66.67%
100-41-4	Ethylbenzene	534	54	29	11	37.93%
100-42-5	Styrene	1,138	45	15	7	46.67%
100-44-7	Benzyl chloride	50	3	3	3	100.00%
101-77-9	4,4'-Methyenedianiline	30	8	9	6	66.67%
106-46-7	1,4-Dichlorobenzene	23	6	6	5	83.33%
106-88-7	1,2-Butylene oxide		2	2	0	0.00%
106-89-8	Epichlorohydrin	79	6	3	1	33.33%
108-88-3	Toluene	3,704	106	67	21	31.34%
108-90-7	Chlorobenzene	66	9	5	5	100.00%
117-81-7	Di-(2-ethylhexyl) phthalate	270	12	9	6	66.67%
117-84-0	n-Dioctyl phthalate	84	3	3	2	66.67%
120-82-1	1,2,4-Trichlorobenzene	56	9	3	3	100.00%
123-31-9	Hydroquinone	61	6	8	1	12.50%
126-99-8	Chloroprene	15	6	5	3	60.00%
131-11-3	Dimethyl phthalate	51	6	4	3	75.00%
615-05-4	2,4-Diaminoanisole	1	1	1	0	0.00%
7440-36-0	Antimony	136	7	7	3	42.86%
7664-39-3	Hydrogen fluoride	500	27	15	3	20.00%
	TOTAL	13,164	463	302	159	52.65%

APPENDIX A
THE PMN REPORTING FORM

O M B No 2070-0012 Approval Expires [illegible]

PREMANUFACTURE NOTICE

FOR NEW CHEMICAL SUBSTANCES

AGENCY USE ONLY

Date of receipt

When completed send this form to

DOCUMENT CONTROL OFFICER
OFFICE OF TOXIC SUBSTANCES, TS-790
U.S. E.P.A.
401 M STREET, SW
WASHINGTON, D.C. 20460

Enter the total number of pages in the Premanufacture Notice

Document control number

EPA case number

GENERAL INSTRUCTIONS

TS- ☐☐☐☐☐☐☐

- You *must provide* all information requested in this form to the extent that it is known to or reasonably ascertainable by you. Make reasonable estimates if you do not have actual data.
- Before you complete this form, you should read the "Instructions Manual for Premanufacture Notification" (Instructions Manual).
- If a user fee has been remitted for this notice (40 CFR 700.45), indicate in the TS boxes above the TS-user fee identification number you have generated. Remember, your user fee ID number must also appear on your corresponding fee remittance.

Part I – GENERAL INFORMATION

You must provide the chemical identity of the new chemical substance, even if you claim the identity as confidential. You may authorize another person to submit the identity for you, but your submission will not be complete and review will not begin until EPA receives this information. A letter of support from another person should reference your TS user fee identification number.

Part II – HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE

You may send additional copies of part II, sections A and B if there are several manufacture, processing, or use operations that you will describe in the notice. You should reproduce these sections as needed.

Part III – LIST OF ATTACHMENTS

You should attach additional sheets if you do not have enough space on the form to answer a question fully. Label each continuation sheet with the corresponding section heading. In part III, list these attachments, any test data or other data and any optional information that you include in the notice.

OPTIONAL INFORMATION

You may include in the notice any information that you want EPA to consider in evaluating the new substance. The Instructions Manual identifies categories of optional information that you may want EPA to review. On page 11 of this form, space has been provided for you to describe pollution prevention and recycling information you may have regarding the new substance.

Binding Options: In order to effectively implement risk management options, EPA may wish to consider its authority under section 5(e) to make certain statements in your notice such as use, production volume, protective equipment and/or process description legally binding and enforceable. If you wish to initiate such discussions with the EPA, precisely describe those aspects in this notice deliberately designed to protect against unreasonable risk to human health or the environment and indicate your willingness to be bound to the appropriate statements by marking OO in the boxes provided. Should the Agency wish to pursue this option, you will be contacted by an EPA *staff* person.

CONFIDENTIALITY CLAIMS

You may claim any information in this notice as confidential. To assert a claim on the form, mark OO the confidential box next to the information that you claim as confidential. To assert a claim in an attachment, circle or bracket the information you claim as confidential. If you claim information in the notice as confidential, you must provide a sanitized version of the notice, including attachments, to EPA with your submission. For additional instructions on claiming information as confidential, read the Instructions Manual.

☐ Mark OO if any information in this notice is claimed as confidential

TEST DATA AND OTHER DATA

You are required to submit all test data in your possession or control and to provide a description of all other data known to or reasonably ascertainable by you if these data are related to the health and environmental effects of the manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance. Standard literature citations may be submitted for data in the open scientific literature. Complete test data (written in English), not summaries of data, must be submitted if they do not appear in the open literature. Following are examples of test data and other data. You should submit these data according to the requirements of §720.50 of the Premanufacture Notification Rule (40 CFR Part 720).

Test Data (See Appendix A of the Instructions Manual and the Physical and Chemical Properties Worksheet on the last page of this form for examples of data to be submitted).

- Environmental fate data ☐ Yes ☐ No
- Health effects data ☐ Yes ☐ No
- Environmental effects data ☐ Yes ☐ No
- Physical/Chemical Properties ☐ Yes ☐ No

Other data ☐ Yes ☐ No

- Risk assessments
- Structure/activity relationships
- Test data not in the possession or control of the submitter

TYPE OF NOTICE (Check Only One)

☐ PMN

☐ CONSOLIDATED PMN - # OF CHEMICALS _____
(Premarket Communication # required, enter # on page 3)

☐ SNUN (Significant New Use Notice)

☐ INTERMEDIATE PMN - AS DEFINED AT 40 CFR 700.43

☐ TMEA (Test Marketing Exemption)

☐ LVE (Low Volume Exemption)

☐ POLYMER EXEMPTION - ☐ (1) or ☐ (2)

☐ OTHER EXEMPTION - SPECIFY

_____

C00073

CERTIFICATION

I certify that to the best of my knowledge and belief:

1. The company named in Part I, section A, subsection 1a of this notice form intends to manufacture or import for a commercial purpose, other than in small quantities solely for research and development, the substance identified in Part I, Section B.

2. All information provided in this notice is complete and truthful as of the date of submission.

3. I am submitting with this notice all test data in my possession or control and a description of all other data known to or reasonably ascertainable by me as required by §720.50 of the Premanufacture Notification Rule.

Additional Certification Statements:

If you are submitting a PMN, (including a polymer exemption notice in accordance with 40 CFR 723.250), Intermediate PMN, Consolidated PMN, or SNUN, check the following user fee certification statement that applies:

☐ The Company named in Part I, Section A has remitted the fee specified in 40 CFR 700.45 (b), or

☐ The Company named in Part I, Section A is a small business concern under 40 CFR 700.43 and has remitted a fee of $100 in accordance with 40 CFR 700.45 (b).

If you are submitting a polymer exemption notice in accordance with 40 CFR 723.250, check the following:

☐ The new chemical substance meets the definition of polymer, is not specifically excluded from the exemption, and meets the conditions of the exemption.

If you are submitting a low volume exemption application in accordance with 40 CFR 723.50, check the following certification statements:

☐ The manufacturer submitting this notice intends to manufacture or import the new chemical substance for commercial purposes, other than in small quantities solely for research and development, under the terms of 40 CFR 723.50.

☐ The manufacturer is familiar with the terms of this section and will comply with those terms; and

☐ The new chemical substance for which the notice is submitted meets all applicable exemption conditions.

The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 USC 1001.

		Confidential
Signature and title of Authorized Official (Original Signature Required)	Date	
Signature of agent - (if applicable)	Date	

Part I – GENERAL INFORMATION

Section A – SUBMITTER IDENTIFICATION

Mark (X) the "Confidential" box next to any subsection you claim as confidential.

1a. Person Submitting Notice (in U.S.)

Name of authorized official | Title

Company

Mailing address (number and street)

City, State, ZIP Code

b. Agent (if applicable)

Name of authorized official | Title

Company

Mailing address (number and street)

City, State, ZIP Code | Telephone: Area Code | Number

c. If you are submitting this notice as part of a joint submission, mark (X) this box. → ☐

Joint Submitter (if applicable)

Name of authorized official | Title

Company

Mailing address (number and street)

City, State, ZIP Code | Telephone: Area Code | Number

2. Technical Contact (in U.S.)

Name | Title

Company

Mailing address (number and street)

City, State, ZIP Code | Telephone: Area Code | Number

3. If you have had a premanufacture communication (PC) concerning this substance and EPA assigned a PC Number to the notice, enter the number ►		Mark (X) if none → ☐
4. If you have submitted an exemption notice/application for the chemical substance covered by this notice, enter the exemption number assigned by EPA. If you have withdrawn a previously submitted PMN enter the PMN number. ►		Mark (X) if none → ☐
5. If you have submitted a bona fide request for the chemical substance covered by this notice, enter the bona fide request number assigned by EPA. → ►		Mark (X) if none → ☐

6. Type of Notice – Mark (X)

☐ Manufacture Only

☐ Binding Opinion Mark (x)

☐ Import Only

☐ BindingOpinon Mark (x)

☐ Both

C00075

Part I – GENERAL INFORMATION – Continued

Section B – CHEMICAL IDENTITY INFORMATION

Mark (X) the "Confidential" box next to any item you claim as confidential.

Complete either item 1 (Class 1 or 2 substances) or 2 (Polymers) as appropriate. Complete all other items.

If another person will submit chemical identity information for you (for either item 1 or 2), mark (X) the box at the right. Identify the name, company, and address of that person in a continuation sheet. → ☐

Confi-dential

1. Class 1 or 2 chemical substances (for definitions of class 1 and class 2 substances, see the Instructions Manual)

a. Class of substance – Mark (X) 1 ☐ Class 1 or 2 ☐ Class 2

b. Chemical name (preferably CAS or IUPAC nomenclature)

c. Molecular formula and CAS Registry Number (if known)

CAS #

d. For a class 1 substance, provide a structural diagram. For a class 2 substance – (1) List the immediate precursor substances with their respective CAS Registry Numbers. (2) Describe the nature of the reaction or process. (3) Indicate the range of composition and the typical composition (where appropriate). (4) Provide a representative structural diagram (if possible).

☐ Mark (X) this box if you attach a continuation sheet.

C00076

Part I – GENERAL INFORMATION – Continued

Section B – CHEMICAL IDENTITY INFORMATION – Continued

2. Polymers (For a definition of polymer, see the Instructions Manual)

Confi-dennal

a. Indicate the number-average weight of the lowest molecular weight composition of the polymer you intend to manufacture. Indicate maximum weight percent of low molecular weight species (not including residual monomers, reactants, or solvents) below 500 and below 1,000 absolute molecular weight of that composition. Describe the methods of measurement or the bases for your estimates. CPC ☐ Other ☐ (Specify)

- lowest number average molecular weight
- maximum weight % below 500 molecular weight
- maximum weight % below 1000 molecular weight

☐ Mark (X) this box if you attach a continuation sheet.

b. You must make separate confidentiality claims for monomer or other reactant identity, composition information, and residual information. Mark (X) the "Confidential" box next to any item you claim as confidential.

(1) – Provide the chemical name and CAS Registry Number of each monomer or other reactant used in the manufacture of the polymer.
(2) – Mark (X) this column if entry in column (1) is confidential.
(3) – Indicate the typical weight percent of each monomer or other reactant in the polymer.
(4) – Mark (X) the identity column if you want a monomer or other reactant used at two weight percent or less to be listed as part of the polymer description on the TSCA Chemical Substance Inventory.
(5) – Mark (X) this column if entries in columns (3) and (4) are confidential.
(6) – Indicate the maximum weight percent of each monomer or other reactant that may be present as a residual in the polymer as manufactured for commercial purposes.
(7) – Mark (X) this column if entry in column (6) is confidential.

Monomer or other reactant and CAS Registry Number (1)	Confi-dential (2)	Typical composition (3)	Identity Mark (X) (4)	Confi-dential (5)	Maximum residual (6)	Confi-dential (7)
		%			%	
		%			%	
		%			%	
		%			%	
		%			%	
		%			%	
		%			%	

☐ Mark (X) this box if you attach a continuation sheet.

c. Provide a representative structural diagram of the polymer, if possible.

☐ Mark (X) this box if you attach a continuation sheet.

Part I – GENERAL INFORMATION – Continued

Section B – CHEMICAL IDENTITY INFORMATION – Continued

Impurities

(a) – Identify each impurity that may be reasonably anticipated to be present in the chemical substance as manufactured for commercial purposes. Provide the CAS Registry Number if available. If there are unidentified impurities, enter "unidentified."

(b) – Estimate the maximum weight % of each impurity. If there are unidentified impurities, estimate their total weight %.

Impurity and CAS Registry Number (a)	Maximum percent (b)	Confidential
	%	
	%	
	%	
	%	
	%	
	%	
	%	

☐ Mark (X) this box if you attach a continuation sheet.

4. Synonyms – Enter any synonyms for the new chemical substance identified in subsection 1 or 2. Confidential

☐ Mark (X) this box if you attach a continuation sheet.

5. Trade identification – List trade names for the new chemical substance identified in subsection 1 or 2.

☐ Mark (X) this box if you attach a continuation sheet.

6. Generic chemical name – If you claim chemical identity is confidential, you must provide a generic chemical name for your substance that reveals the specific chemical identity of the new chemical substance to the maximum extent possible. Refer to the TSCA Chemical Substance Inventory, 1985 Addition, Appendix B for guidance on developing generic names.

☐ Mark (X) this box if you attach a continuation sheet.

7. Byproducts – Describe any byproducts resulting from the manufacture, processing, use, or disposal of the new chemical substance at sites you control. Provide the CAS Registry Number if available.

Byproduct (1)	CAS Registry Number (2)	Co den

☐ Mark (X) this box if you attach a continuation sheet.

Part I – GENERAL INFORMATION – Continued

Section C – PRODUCTION, IMPORT, AND USE INFORMATION

Mark (X) the "Confidential" box next to any item you claim as confidential.

1. Production volume – Estimate the maximum production volume during the first 12 months of production. Also estimate the maximum production volume for any consecutive 12 month period during the first three years of production.

Maximum first 12-month production (kg/yr)	Maximum 12-month production (kg/yr)	Confidential	Binding Option Mark (x)

2. Use Information – You must make separate confidentiality claims for the description of the category of use, the percent of production volume devoted to each category, the formulation of the new substance, and other use information. Mark (X) the "Confidential" Box next to any item you claim as confidential.

a. (1) – Describe each intended category of use of the new chemical substance by function and application.
(2) – Mark (X) this column if entry in column (1) is confidential business information (CBI).
(3) – Indicate your willingness to have the information provided in column (1) binding.
(4) – Estimate the percent of total production for the first three years devoted to each category of use.
(5) – Mark (X) this column if entry in column (4) is confidential business information (CBI).
(6) – Estimate the percent of the new substance as formulated in mixtures, suspensions, emulsions, solutions, or gels as manufactured for commercial purposes at sites under your control associated with each category of use.
(7) – Mark (X) this column if entry in column (6) is confidential business information (CBI).
(8) – Mark (X) whether the use is site-limited, industrial, commercial and/or consumer. Mark more than one box if appropriate. Mark (X) to indicate your willingness to have the information provided in (8) binding.
(9) – Mark (X) this column if entry(ies) in column (8) is (are) confidential business information (CBI).

Category of use (1)	CBI (2)	Binding Option Mark (x) (3)	Production % (4)	CBI (5)	% in Formulation (6)	CBI (7)	Mark (X) appropriate column(s) (8) Site-limited	Consumer*	Industrial	Commercial	Binding Option	CBI (9)
			%		%							
			%		%							
			%		%							
			%		%							
			%		%							

*If you have identified a "consumer" use, please provide on a continuation sheet a detailed description of the use(s) of this chemical substance in consumer products. In addition include estimates of the concentration of the new chemical substance as expected in consumer products and describe the chemical reactions by which this substance loses its identity in the consumer product.

☐ Mark (X) this box if you attach a continuation sheet.

b. Generic use description

If you claim any category of use description in subsection 2a as confidential, enter a generic description of that category. Read the Instructions Manual for examples of generic use descriptions.

☐ Mark (X) this box if you attach a continuation sheet.

3. Hazard Information – Include in the notice a copy of reasonably foreseeable hazard warning statement, label, material safety data sheet or other information which will be provided to any person who is reasonably likely to be exposed to this substance regarding protective equipment or practices for the safe handling, transport, use, or disposal of the new substance. List in part III hazard information you include.

☐ Mark (X) this box if you attach hazard information.

C00079

Part II – HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE

ction A – INDUSTRIAL SITES CONTROLLED BY THE SUBMITTER

mplete section A for each type of manufacture, processing, or use operation involving the new chemical bstance at industrial sites you control.

Mark (X) the "Confidential" box next to any item you claim as confidential.

Operation description

a. Identity – Enter the identity of the site at which the operation will occur. | Confidential

Name

Site address (number and street)

City, County, State, ZIP Code

If the same operation will occur at more than one site, enter the number of sites. Identify the additional sites on a continuation sheet. →

☐ Mark (X) this box if you attach a continuation sheet.

b. Type – Mark (X) ☐ Manufacturing ☐ Processing ☐ Use

c. Amount and Duration – Complete 1 or 2 as appropriate

1. Batch	Maximum kg/batch	Hours/batch	Batches/year
2. Continuous	Maximum kg/day	Hours/day	Days/year

d. Process description ☐ Mark (X) to indicate your willingness to have your process description binding.

(1) Diagram the major unit operation steps and chemical conversions.
(2) Provide the identity, the approximate weight (by kg/day or kg/batch), and entry point of all feedstocks (including reactants, solvents, and catalysts, etc.).
(3) Identify by number the points of release to the environment of the new chemical substance.

☐ Mark (X) this box if you attach a continuation sheet.

Section A – INDUSTRIAL SITES CONTROLLED BY THE SUBMITTER – Continued

2. Occupational Exposure – You must make separate confidentiality claims for the description of worker activity, physical form of the new chemical substance, number of workers exposed, and duration of activity. Mark (X) the "Confidential" box next to any item you claim as confidential.
(1) – Describe the activities in which workers may be exposed to the new chemical substance.
(2) – Mark (X) this column if entry in column (1) is confidential business information (CBI).
(3) – Describe any protective equipment and engineering controls used to protect workers.
(4) and (6) – Indicate you willingness to have the information provided in column (3) or (5) binding.
(5) – Indicate the physical form(s) of the new chemical substance at the time of exposure.
(7) – Mark (X) this column if entry in column (5) is confidential business information (CBI).
(8) – Estimate the maximum number of workers involved in each activity.
(9) – Mark (X) this column if entry in column (8) is confidential business information (CBI).
(10) and (11) – Estimate the maximum duration of the activity for any worker in hours per day and days per year.
(12) – Mark (X) this column if entries in columns (10) and (11) are confidential business information (CBI).

Worker activity (1)	CBI (2)	Protective Equipment/ Engineering Controls (3)	Binding Option Mark (x) (4)	Physical form(s) (5)	Binding Option Mark (x) (6)	CBI (7)	# of Workers Exposed (8)	CBI (9)	Maximum duration		CBI (12)
									Hrs/day (10)	Days/yr (11)	

☐ Mark (X) this box if you attach a continuation sheet.

3. Environmental Release and Disposal – You must make separate confidentiality claims for the release number and the amount of the new chemical substance released and other release and disposal information. Mark (X) the "Confidential" box next to each item you claim as confidential.
(1) – Enter the number of each release point identified in the process description, part II, section A, subsection 1d(3).
(2) – Estimate the amount of the new substance released (a) directly to the environment or (b) into control technology (in kg/day or kg/batch).
(3) – Mark (X) this column if entries in columns (1) and (2) are confidential business information (CBI).
(4) – Identify the media (air, land, or water) to which the new substance will be released from that release point.
(5) – a. Describe control technology, if any, and control efficiency that will be used to limit the release of the new substance to the environment. For releases disposed of on land, characterize the disposal method and state whether it is approved for disposal of RCRA hazardous waste. On a continuation sheet, for each site describe any additional disposal methods that will be used and whether the waste is subject to secondary or tertiary on-site treatment. b. Estimate the amount released to the environment after control technology (in kg/day).
(6) – Mark (X) this column if entries in columns (4) and (5) are confidential business information (CBI).
(7) – Identify the destination(s) of releases to water. Please supply NPDES (National Pollutant Discharge Elimination System) numbers for direct dischargers or NPDES numbers of the POTW (Publicly Owned Treatment Works). Mark (X) if the POTW name or NPDES # is confidential business information (CBI).

Release Number (1)	Amount of new substance released (2a)	(2b)	CBI (3)	Media of release (4)	Control technology and efficiency (5a)	Binding Mark (x)	(5b)	C (6)

(7) Mark (X) the destination(s) of releases to water.	☐ POTW provide name(s) below: _____	CBI	☐ Navigable waterway	☐ Other - Specify	NPDES #

☐ Mark (X) this box if you attach a continuation sheet.

C00081

Part II – HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE – Continued

Section B – INDUSTRIAL SITES CONTROLLED BY OTHERS

Complete section B for typical processing or use operations involving the new chemical substance at sites you do not control. Complete a separate section B for each type of processing, or use operation involving the new chemical substance. If the same operation is performed at more than one site describe the typical operations common to these sites and enter the number of sites _____. Identify additional sites on a continuation sheet.

1 Operation Description - To claim information in this section as confidential, circle or bracket the specific information that you claim as confidential.
(1) – Diagram the major unit operation steps and chemical conversions. On the diagram, identify by letter and briefly describe each worker activity.
(2) – Provide the identity, the approximate weight (by kg/day or kg/batch), and entry point of all feedstocks (including reactants, solvents, and catalysts, etc). (3) – Identify by number the points of release to the environment of the new chemical substance.

☐ Mark (X) this box if you attach a continuation sheet.

2. Worker Exposure/Environmental Release.
(1) – From the diagram above, provide the letter for each worker activity. Complete 2-8 for each worker activity described.
(2) – Estimate the number of workers exposed.
(4) – Estimate the typical duration of exposure per worker in (a) hours per day and (b) days per year.
(6) – Describe any protective equipment and engineering controls, if any, used to protect workers.
(7) – Estimate the percent of the new substance as formulated when packaged or used as a final product.
(9) – From the process diagram above, enter the number of each release point. Complete 9-13 for each release point identified.
(10) – Estimate the amount of the new substance released (a) directly to the environment or (b) into control technology to the environment (in kg/day or kg/batch).
(12) – Describe control technology, if any, that will be used to limit the release of the new substance to the environment.
(14) – Identify byproducts which may result from the operation.
(3), (5), (8), (11), (13) and (15) - Mark (X) this column if any of the preceding entries are confidential business information (CBI).

Letter of Activity (1)	# of Workers Exposed (2)	CBI (3)	Duration of Exposure (4a)	(4b)	CBI (5)	Protective Equip./ Engineering Controls (6)	% in Formulation (7)	CBI (8)	Release Number (9)	Amount of New Substance Released (10a)	(10b)	CBI (11)	Control Technology (12)

(14) – Byproducts:

☐ Mark (X) this box if you attach a continuation sheet.

OPTIONAL POLLUTION PREVENTION INFORMATION

To claim information in this section as confidential circle or bracket the specific information that you claim as confidential

In this section you **may** provide information not reported elsewhere in this form regarding your efforts to reduce or minimize potential risks associated with activities surrounding manufacturing, processing, use and disposal of the PMN substance. Please include new information pertinent to pollution prevention, including source reduction, recycling activities and safer processes or products available due to the new chemical substance. Source reduction includes the reduction in the amount or toxicity of chemical wastes by technological modification, process and procedure modification, product reformulation, raw materials substitution, and/or inventory control. Recycling refers to the reclamation of useful chemical components from wastes that would otherwise be treated or released as air emissions or water discharges, or land disposal. Descriptions of pollution prevention, source reduction and recycling should emphasize potential risk reduction subsequent to compliance with existing regulatory requirements and can be either quantitative or qualitative. The EPA is interested in this information to assess overall net reductions in toxicity or environmental releases and exposures, not the shifting of risks to other environmental media or non-environmental areas (e.g., occupational or consumer exposure). In addition, information on the relative cost or performance characteristics of the PMN substance to potential alternatives may be provided. **All information provided in this section will be taken into consideration during the review of this substance.**

Describe the expected net benefits, such as (1) an overall reduction in risk to human health or the environment; (2) a reduction in the volume manufactured; (3) a reduction in the generation of waste materials through recycling, source reduction or other means; (4) a reduction in potential toxicity or human exposure and/or environmental release; (5) an increase in product performance, a decrease in the cost of production and/or improved operation efficiency of the new chemical substance in comparison to existing chemical substances used in similar applications; or (6) the extent to which the new chemical substance may be a substitute for an existing substance that poses a greater overall risk to human health or the environment.

☐ Mark (X) this box if you attach a continuation sheet.

Part III – LIST OF ATTACHMENTS

Attach continuation sheets for sections of the form and test data and other data (including physical/chemical properties and structure/activity information), and optional information after this page. Clearly identify the attachment and the section of the form to which it relates, if appropriate. Number consecutively the pages of the attachments. In the column below, enter the inclusive page numbers of each attachment.

Mark (X) the "Confidential" box next to any attachment name you claim as confidential. Read the Instructions Manual for guidance on how to claim any information in an attachment as confidential. You must include with the sanitized copy of the notice form a sanitized version of any attachment in which you claim information as confidential.

Attachment name	Attachment page number(s)	Confidential

☐ Mark (X) this box if you attach a continuation sheet. Enter the attachment name and number.

C00084

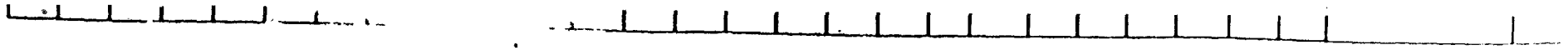
PHYSICAL AND CHEMICAL PROPERTIES WORKSHEET

To assist EPA's review and include it in the of the property, th confidential. Yo review and e your subm

physical and chemical properties data, please complete the following worksheet for data you provide
. Identify the property measured, the page of the notice on which the property appears, the value which the property is measured (as necessary), and whether or not the property is claimed as
quired to submit this worksheet; however, EPA strongly recommends that you do so, as it will simplify
dential information is properly protected. You should submit this worksheet as a supplement to
This worksheet is not a substitute for submission of test data.

Section B
2. Polymer
a. Indic
Ind
Sp

	Mark (X) if provided	Page number (b)	Value (c)	Confidential Mark (X) (d)
Vapor pressure ● Temperature ___ ℃			Torr	
Density/relative density			g/cm3	
Solubility ● Temperature ___ ℃ Solvent ___			g/L	
Solubility in water ● Temperature ___ ℃			℃	
Melting temperature			℃	
Boiling/sublimation temperature ● ___ torr pressure				
Spectra				
Dissociation constant				
Particle size distribution				
Octanol/water partition coefficient				
Henry's Law constant				
Volitalization from water				
Volitalization from soil				
pH ● concentration ___				
Flammability				
Explodability				
Adsorption/coefficient				
Other - Specify				



APPENDIX B
THE NEW CHEMICALS (PMN) PROGRAM

When submitting a PMN, companies must provide such information as a structural diagram (if the substance can be represented by one), chemical name, CAS Registry Number (if available), and molecular formula. Other information reported includes the impurities anticipated to be present in the substance, any known synonyms or trade names, the estimated maximum amount to be manufactured or imported during the first year of production and during any 12-month period during the first three years of production, and a description of the intended categories of use by function and application. Additional information may be reported depending on whether or not the site is controlled by the submitter. Such information would include specific site information as well as a description of the operations involved in manufacture, processing and use, worker exposure information, physical form of the new substance to which workers may be exposed, the number of workers and the duration of activities, and information on release of the new substance to the environment (40 CFR 720.45). The submitter must also send any available test data related to the effects on health or the environment.

Based on the information provided in the PMN form (see Appendix A), EPA must assess the risks to ascertain if the chemical may or will pose an unreasonable risk to human health or the environment. EPA's assessment is highly dependent on the quality of information submitted. Even though it is EPA's responsibility to determine chemical risk, EPA cannot require manufacturers to perform testing of new chemicals *unless* it has made a determination that the chemical may or will pose an unreasonable risk. Based on the information received in the PMN, EPA has four options with regard to the substance.

1. It can do nothing and the chemical may be manufactured without restriction, subject to the manufacturer providing notice to EPA via a Notice of Commencement.

2. The Agency can issue a significant new use rule (SNUR) which requires manufacturers or processors to notify EPA in the future if they intend to process or produce a chemical for uses beyond those stated in the original PMN. The Significant New Use Notice must be submitted 90 days before commencing manufacture, import, or processing of the chemical substance for the new use.

3. Under Section 5(e), EPA can issue an administrative order or obtain an injunction to regulate the manufacture, processing, distribution, or disposal of the new substance pending the development of new information. Section 5(e) may be invoked only if EPA determines that the chemical *may* pose an unreasonable risk, in that information received in the PMN is insufficient to make a finding with respect to its health or environmental effects.

4. If EPA finds that a chemical *will* pose an unreasonable risk, it may act under section 5(f) to limit or prohibit the chemical's manufacture, sale, use, or disposal.

<u>Examination of the Generic Chemical Name by EPA (40 CFR 720.85 (a)(3))</u>

If the chemical identity of a new chemical is claimed as confidential, the submitter must provide a generic name at the time of the claim. EPA will examine the generic chemical name proposed by the submitter claiming confidentiality. The generic name proposed by the submitter must be only as generic as necessary to protect the confidential identity of the particular chemical substance. The name should reveal the specific chemical identity to the maximum extent possible. If EPA approves of the generic name, it will be placed on the inventory. If the name is more generic than necessary to protect the confidential identity, EPA will notify the submitter within 30 days that further consultation is necessary.

PMN Exemptions

Exemptions to the PMN process are made for polymers, chemicals developed solely for use in research and development, and chemicals distributed solely for test marketing purposes. Substances developed for test marketing may be exempted if there is a finding that the chemical in commerce "will not present any unreasonable risk of injury to health or the environment..." (Section 5(h)(1)(A),(B)).

When a company is reporting a new chemical, it may exempt itself from pre-manufacture notification requirements if the particular chemical substance is not included in the public inventory but falls within one of the generic chemical names in the appendix entitled "confidential identities." The submitter may ask EPA whether the substance is on the inventory and EPA will provide the answer if the submitter has a *bona fide* intent to manufacture the substance. In order to establish a *bona fide* intent to manufacture (40 CFR 710.7 (g)(2)) a specific chemical substance, the person proposing to manufacture this substance must submit to EPA:

1. A signed statement that the person intends to manufacture the substance for commercial purposes;

2. A description of the research and development activities he has conducted to date and the purposes for which the substance will be manufactured;

3. An elemental analysis;

4. Either an X-ray diffraction pattern (for inorganic substances) or a mass spectrum (for most other substances) of the particular chemical substance;

5. A sample of the substance in its purest form, if requested; and,

6. Any additional or alternative spectra, or other data that may be required to resolve uncertainties with respect to the identity of the chemical substance.

Once a *bona fide* intent has been determined by EPA, a comparison will be made between the generic substance listed on the inventory and the substance being newly reported. If the comparison of the elemental analysis and either the X-ray diffraction patterns or mass or alternative spectra is sufficiently similar to be consistent with a presumption that the chemical substances are the same and comparison of any of the other submitted information affirms this, EPA will tell the submitter proposing to manufacture the particular chemical substance that the particular chemical substance is included on the inventory and that pre-manufacture notice is not required (40 CFR 710.7 (g)(5)). If the comparison of either the X-ray diffraction patterns or the mass or alternative spectra does not prove that the chemical substances are the same, and comparison of the other information affirms this conclusion, then pre-manufacture notice is required (40 CFR 710.7 (g)(6)), since the substance is deemed not to be included on the inventory.

A manufacturer may also apply for an exemption for a new chemical (or category of chemicals) from all or part of the PMN requirements. This exemption may be granted under section 5(h)(4) if EPA determines that the use of this chemical in commerce will not present an "unreasonable risk of injury to health of the environment." Section 5(h)(4) exemptions require formal rulemaking.

APPENDIX C
REPORTING AND RECORD-KEEPING (SECTION 8)

Section 8 of TSCA gives EPA the ability to collect information on existing chemicals (*i.e.* chemicals in commerce). Section 8(a) allowed EPA to promulgate rules under which chemical manufacturers are required to maintain records and report the following information (Section 8(a)(2)):

- the common or trade name, the chemical identity, and the molecular structure of each chemical substance;
- the categories or proposed categories of use;
- the total volume under existing uses with projected volumes for proposed uses;
- a description of the byproducts resulting from commercial chemical use;
- all existing data concerning the environmental and health effects;
- exposure data; and,
- the manner of method of disposal and any change in the manner or method of disposal.

Claims of confidentiality are made according to the general procedure. If the company fails to provide a second (sanitized) copy of the notice, EPA notifies the submitter by certified mail. The submitter must send the second copy within 15 days of being notified; otherwise, the confidentiality claimed is waived and the first copy may be placed in the public file (40 CFR 704.7 (c)(4)).

Other Chemical Information Rules (40 CFR 712)

The chemical information rules as stated in 40 CFR 712 establish procedures for chemical manufacturers and processors to report production, use, and exposure-related information on listed chemical substances. Chemical substances, mixtures, and categories of substances or mixtures which have been recommended by the Interagency Testing Committee for testing consideration by the Agency but not designated for Agency response within 12 months are included for reporting under this rule, only to the extent that the total number of designated and recommended chemicals does not exceed 50 in any one year. Under the chemical information rules, any information reported on the appropriate form may be claimed as confidential, and substantiation requirements are met by checking the appropriate boxes on the form. If no claim accompanies the information at the time the form is submitted, it is placed in the public file without further notice (40 CFR 712.15(c)).

Partial Updating of the Inventory Data Base (40 CFR 710 Subpart B)

The Master Inventory File is EPA's comprehensive list of chemical substances which constitutes the Chemical Substances Inventory compiled under section 8(b) of TSCA. It includes chemical substances reported under the initial inventory reporting requirements as well as substances reported under the pre-manufacture notification program for which a Notice of Commencement of Manufacture or Import has been received. The first update for the 1977 TSCA inventory occurred in 1986. The next reporting period was 1990 and subsequent reporting periods will occur at four year intervals thereafter (40 CFR

710.33). Updated information must be reported for chemicals which do not fall into one of four broad classes:

- inorganic chemical substances;
- polymers;
- microorganisms; and,
- naturally occurring chemical substances.

APPENDIX D
HAZARDOUS CHEMICALS IDENTIFIED UNDER THE ACT

Once EPA finds that a chemical poses an unreasonable risk to human health or the environment, it has a variety of options under Section 6 to control the commercial use of that chemical. EPA may apply any of these options by rule "to the extent necessary to protect adequately against such risk using the least burdensome requirements." Among these options (summarized below) are some that require the public dissemination of risk-relevant information (emphasis added):

- prohibiting or limiting the commercial use of the chemical substance or mixture;
- prohibiting or limiting the commercial use of the chemical substance or mixture for a particular use or for a particular use in a concentration in excess of a level specified by EPA;
- *requiring that the chemical substance be labelled* with clear and adequate warnings with respect to its use or disposal;
- requiring that manufacturers of the substance make and retain records of the processes used to manufacture the substance and monitor and conduct tests which are necessary to assure compliance with any rule that EPA has promulgated;
- prohibiting or regulating any manner or method of disposal of the chemical substance;
- *requiring manufacturers or processors of the chemical substance or mixture to provide notice* of unreasonable risk of injury to anyone who may come in contact with the chemical substance, *to give public notice* of such risk, and to replace or repurchase the chemical substance or mixture, whichever is chosen by the person to which this requirement is directed.

Asbestos

By rule, EPA requires reporting by persons who manufacture, import, or process asbestos and asbestos-containing products. Different reporting requirements are imposed depending on the person's activity. Manufacturers, importers, and processors of commercial and industrial asbestos fiber must report quantity, use, and exposure information. Importers of mixtures and articles containing asbestos and processors of asbestos mixtures also report to EPA in two phases (40 CFR 763.60 (a)). They initially must report limited information about processing or importation. Some must subsequently report additional information if they are selected as respondents in a sample survey. Claims of confidentiality may be made for any information submitted. Certification is made by signing the certification statement specified on the reporting form(s). If no claim accompanies the form at the time the form is submitted, then the information may be placed in a public file without further notice to the submitter (40 CFR 763.74).

In addition to requiring reporting by manufacturers, importers, and processors of asbestos, EPA has identified a list of asbestos-containing products which have been prohibited from manufacture, importation, processing, and distribution in commerce. EPA may grant exemptions for products subject to this rule. In submitting an application for an exemption the submitter reports such information as (summarized): a description of the manufacturing, import, processing, and/or distribution in commerce activity for which an exemption is requested; identification of the locations at which the exempted activity would take place; length of time requested for an exemption (maximum length of exemption is four years); exposure levels over the life cycle of the product; and data concerning the non-asbestos substitute (40 CFR 763.173(d)). Any of the information reported in an exemption application may be

claimed as confidential according to the general procedure. If the submitter fails to submit a second copy of the information, he has 30 days from the date of receipt of notification to submit the second copy, else the information is placed in a public file.

Applicants who assert CBI claims must substantiate all claims by providing detailed written answers to the questions listed below.

1. Is this information subject to a patent or patent application in the United States or elsewhere? If so, why is confidentiality necessary?

2. For what period do you assert a claim of confidentiality? If the claim is to extend until a certain event or point in time, please indicate that event or time period. Explain why such information should remain confidential until such point.

3. Has the information that you are claiming as confidential been disclosed to persons outside of your company? Will it be disclosed to such persons in the future? If so, what restrictions, if any, apply to use or further disclosure of the information?

4. Briefly describe measures taken by your company to guard against undesired disclosure of the information you are claiming as confidential to others.

5. Does the information claimed as confidential appear or is it referred to in advertising or promotional materials for the product or the resulting end product, safety data sheets or other similar materials for the product or the resulting end product, professional or trade publications, or any other media available to the public or to your competitors? If you answered yes, indicate where the information appears.

6. If the Agency disclosed the information you are claiming as confidential to the public, how difficult would it be for the competitor to enter the market for your product? Consider in your answer such constraints as capital and marketing cost, specialized technical expertise, or unusual processes.

7. Has the Agency, another Federal agency, or a Federal court made any confidentiality determination regarding this information? If so, provide copies of such determinations.

8. How would your company's competitive position be harmed if the Agency disclosed this information? Why should such harm be considered substantial? Describe the causal relationship between the disclosure and harm.

9. In light of section 14(b) of TSCA, if you have claimed information from a health and safety study as confidential, do you assert that disclosure of this information would disclose a process used in the manufacturing or processing of a product or information unrelated to the effects of asbestos on human health and the environment? If your answer is yes, explain.

APPENDIX E
CBI SECURITY PROCEDURES

The security requirements for CBI are based on four components: Administrative Security, Facility Security, Procedural Requirements, and Audit and Inspection. These components are discussed below.

Administrative Security -

Access to TSCA CBI is granted only on a "need to know" basis, and is limited to EPA employees, EPA contractors and their employees, and others only as explicitly addressed in the statute (see previous section).

- Even EPA grantees (such as those working in the American Association of Retired Persons program alongside EPA staff) and states may not be granted access to TSCA CBI.
- Access to CBI is allowed only for those sections of TSCA for which the employee or contractor has demonstrated need.
- Each EPA employee or contractor employee who requests access to TSCA CBI is subjected to an extensive background investigation, referred to as a National Agency Check and Inquiry (NACI). These investigations are intended to reveal any information that may reflect adversely on an employee's suitability or trustworthiness to handle TSCA CBI.
- Authorized access to CBI is reviewed annually. All employees must attend a CBI procedural review and pass a written test. All senior OPPT staff are reviewed annually to determine conflicts of interest. This review includes full financial disclosure with oversight by the OPPT director.
- All persons given access to CBI must sign a confidentiality agreement, which gives notice of the penalties for willful disclosure of CBI, as provided by the statute.

Facility Security

All facilities handling CBI provide for limited access. Buildings are guarded 24 hours per day, seven days per week.

- Secured areas within EPA may be designated as "open shelf" document storage facilities. These areas are secured through the use of electronic card entry identification badges. Employees who have been issued a card are required to use it each time they enter a card entry secured area.
- Unless CBI material is being used in an approved open storage area, it must be stored in an approved container at the end of the business day or when not in use. CBI material must be stored in a file cabinet with a bar lock and three-way adjustable lock, or GSA-approved Class 6 security container. Each container must also have a Safe/Cabinet Security Check Sheet attached to indicate opening and closing as well as when checked.

Procedural Requirements

Once a document is classified as CBI, it must be logged into a document control system or the TSCA CBI inventory log. It is assigned a document control number and stamped "TSCA Confidential Business Information ... Does not contain National Security Information (E.O. 12065)." A cover sheet is attached which contains the name of the Document Control Officer (DCO), the document control number, and the date of receipt of the original document. The document is tracked until it is either declassified or destroyed.

- If a person authorized for access to CBI wishes to obtain a CBI document, he must go to the Confidential Business Information Center (CBIC) and request the document from the appropriate DCO or Document Control Assistant (DCA). The DCO/DCA verifies that the requester is listed on the TSCA CBI Authorized Access List, and then obtains the document from either local secure storage, another DCO, or an authorized computer facility.

- Each person who retrieves a document containing CBI from the DCO or Document Control Assistant (DCA) must sign the cover sheet. Documents must be charged out on the Document Tracking System or logged out each time the document is removed from the custody of the DCO.

- The employee must either keep the document in his/her possession at all times, return it to the CBIC, or store it in a locked approved storage container.
- Documents containing CBI can not be transferred directly from one person who is cleared for CBI access to another, except for a limited period. To effect a transfer between cleared employees, the person must go through the DCO/DCA by use of a Loan Receipt for TSCA CBI, or the document must be logged back through the CBIC.

- Any copying of documents containing CBI must be performed on a machine that has been cleared for this purpose, under the supervision of a specially-trained Document Control Officer (DCO). With the exception of working paper and draft copies, the DCO/DCA must enter all copies into the Document Tracking System or Inventory Log for document control.

- The destruction of each document containing CBI must be supervised by a DCO and noted in a Destruction Log and the Document Tracking System.

- Declassification of documents or magnetic tape is performed under strict procedures when attempting to satisfy an information request. Declassification also occurs when the submitter who requested that the information be handled as CBI requests that it be declassified. (In actuality, this rarely occurs.)

- All CBI logs must be retained for at least five years from the date of last entry in secure storage.

Automated Data Systems

Automated data systems may only be used to process CBI with elaborate precautions to prevent disclosure of CBI.

- These are located in designated CBI-secure areas. Data lines between these secure areas are secured by means of data encryption or the use of closed conduits.

- Outside of these areas, the operator must retain *exclusive control* of the PC and any peripherals, and must ensure that any CBI contained in non-removable storage media or in the computer's

memory are completely obliterated before relinquishing control of the PC. Even printer ribbons used to print CBI themselves become CBI and must be protected as are documents or computer disks.

- Mainframe computers that process CBI must operate entirely within a CBI environment, and steps must be taken to completely remove all CBI from such a system when transferring from a CBI operating mode to a non-CBI mode.

- Communications lines between computers that carry CBI must be encrypted. Until recently, this applied even to lines passing through non-secure areas within EPA buildings.

Audit and Inspection

Audit and inspection ensures that security procedures in place actually protect CBI.

- The TSCA Security staff investigate violations and provide expertise on physical and computer security issues.

- Periodic and unannounced inspections and audits of facilities are conducted by the TSCA Security staff. CBI documents are also audited annually.

- OPPT conducts periodic evaluations of TSCA CBI security procedures.

TSCA CBI security requires considerable effort. While the TSCA Security Office has a small staff, many of the personnel in the Confidential Data Branch devote a considerable portion of their time to safeguarding CBI. Their responsibilities and the responsibilities of other personnel who handle TSCA CBI are summarized in Table E-1. This table is not an inclusive list of CBI security tasks performed by personnel at EPA, but attempts to highlight the major tasks which are time intensive. Table E-2 provides a list of logs and tracking documents used in creating an audit trail for CBI material.

Table E-1

Task	AA OPTS	Dir. OTS	Dir. IMD	OIG	Dir. OIRM	Gen. Serv. FSSD	Position Title: Div. Dirs.	Position Title: Branch Chiefs	Security IMD	EPA Proj. Off.	DCOs	DCAs	OGC	CIB
Obtaining Authorization For Access									X					
Processing Forms For Access to CBI									X	X				
Approving Contractors For Access to CBI			X						X	X			X	X
Preparing Signing Federal Register Notices		X	X				X							
Ensuring NACIs are conducted for federal employees				X										
Requesting / Removing Employee Access							X							
Investigations and Inspections			X						X					
Initial and Annual Inspection				X										
Inspection of Computer Facilities					X									
Inspection of Physical Security						X								
Maintaining Authorization									X		X	X		
Maintaining the Authorized Access List							X	X						
Annual Security Training								X						
Quarterly Security Discussion								X						
Ensures that employees are properly approved														
Policies and Procedures for Security							X	X						
Overall Implementation of the procedures	X			X				X						
Compliance with procedures and policies			X						X					
Developing new policies and procedures			X		X				X					
Approve / Review Computer Center Security Plans			X		X				X					
Approve / Review ADP Application Security Plans			X								X			
Approve Headquarters DCO, Computer DCO/DCA						X								
Establish written physical security standards														
Document Control								X			X	X		
Proper Storage								X			X	X		
Activity Logs								X						
Sanitizing Staff-Produced Documents										X				
Accounting for all CBI related material used by contractors when a contract ends.											X	X		
Destruction											X	X		
Reproduction											X	X		
Receipt											X	X		
Initial Processing											X	X		
Distribution											X	X		
Control														

Table E-2: LIST OF LOGS AND TRACKING SHEETS USED IN PROTECTING CBI

Inventory Log
User Sign Out Log
Destruction Log
Contractor/Subcontractor Sign Out Log
Federal Agency, Congress, and Federal Court Sign Out Log
Request for TSCA CBI Access Approval
Request for TSCA CBI Computer Access Approval
TSCA CBI Cover Sheet
Telephone Contact Report
TSCA Confidential Business Information Meeting Sign In Sheet
Safe/Cabinet Security Check Sheet
Request for Approval of Contractor Access To TSCA Confidential Business Information
Loan Receipt for TSCA Confidential Business Information

Penalties for Accidental Disclosure of CBI

Although the legislative and statutory language assigns severe penalties for "wrongful" disclosure of CBI, most disclosures within EPA are accidental. In such cases, where the impact of the disclosure is not serious, most employees are not harshly penalized but are counselled as to their actions. Appendix I of the TSCA Confidential Business Security Manual lists informal corrective actions taken. They include: closer supervision, on-the-job training, and oral reprimands. A serious violation may warrant removing the employee from the Authorized Access List. Each case is reviewed on an individual basis.

A review of records of CBI violations maintained by the TSCA security staff indicates that most violations represent failures to follow procedures strictly, and are unlikely to result in the disclosure of CBI to unauthorized persons. Figure E-1 shows that the overall number of violations is quite small, relative to either the number of CBI documents maintained by OPPT or the number of transactions involving CBI documents. By far the greatest number of infractions represent failures to abide by strict document-handling procedures, such as sending a CBI document to another authorized person using interoffice mail, or hand delivery of a document where the transmitter did not actually deliver the document into the hands of the recipient and obtain a signed receipt, or leaving a document within EPA in an improperly secured area. There were occasions on which CBI was placed into a public file or database, but a much greater proportion of infractions reflect situations in which drawers were not locked or audit trails on documents were incomplete.

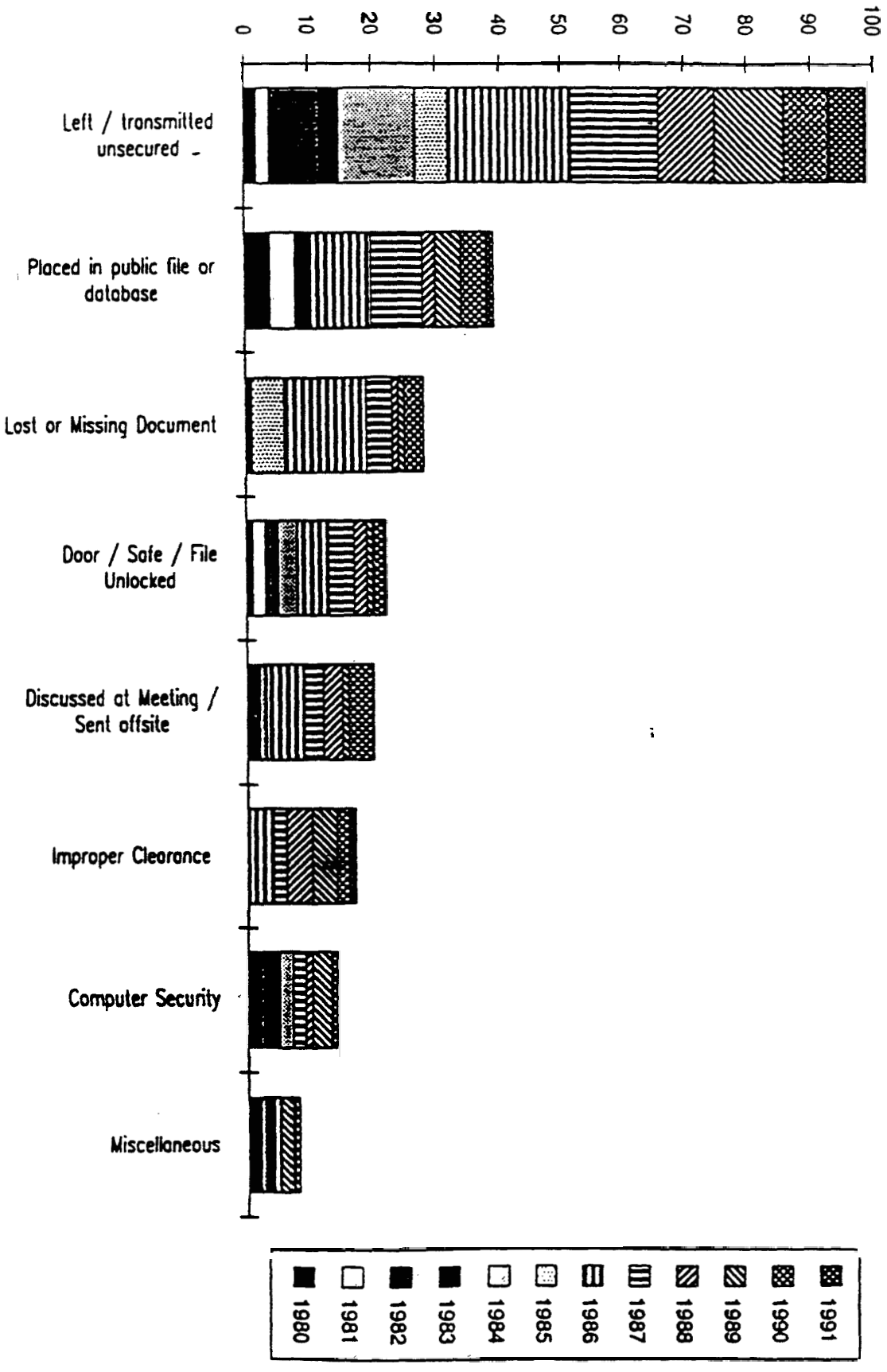

0
10
20
30
40
50
60
70
80
90
100
Left / transmitted unsecured
Placed in public file or database
Lost or Missing Document
Door / Safe / File Unlocked
Discussed at Meeting / Sent offsite
Improper Clearance
Computer Security
Miscellaneous
1980
1981
1982
1983
1984
1985
1986
1987
1988
1989
1990
1991

Figure E-1

APPENDIX F
SCREENING INFORMATION DATA SET (SIDS) CHEMICALS
KNOWN HUMAN CARCINOGENS IDENTIFIED BY NTP

SIDS (Screening Information Data Set) Chemicals for which U.S. is lead country - Phase I and Phase II High Production Volume (HPV) Chemicals

Phase I

- 75-77-4 Silane, chlorotrimethyl-
- 78-84-2 Propanal, 2-methyl
- 123-38-6 Propanal
- 504-60-9 1,3-Pentadiene
- 556-67-2 Cyclotetrasiloxane, octamethyl
- 693-23-2 Dodecanoic acid
- 2402-79-1 Pyridine, 2,3,5,6-tetrachloro
- 25265-77-4 Propanoic acid, 2-methyl, monoester with 2,2,4-trimethyl-1,3-pentanediol
- 29590-42-9 2-Propenoic acid, isooctyl ester

Phase II

- 78-93-3 Methyl Ethyl Ketone {Oral RfD in IRIS, Inhalation RfC in HEAST}
- 108-10-1 Methyl Isobutyl Ketone {Oral RfD and Inhalation RfC in HEAST}
- 111-11-5 Methyl caprylate
- 111-66-0 1-Octene
- 111-82-0 Dodecanoic acid, methyl ester
- 112-41-4 1-Dodecene
- 592-41-6 1-Hexene
- 1120-36-1 1-Tetradecene
- 2524-03-0 Dimethyl chlorothiophosphate
- 2524-04-1 Diethyl chlorothiophosphate
- 4259-15-8 Phosphorodithioic acid, O,O-bis(2-ethylh

Chemicals with Nonmedical Uses That Were Identified as Human Carcinogens in the Fifth Annual Report on Carcinogens (NTP 89-239), 1989 (The most recent such report)

- 92-67-1 4-Aminobiphenyl
- 7440-38-2 Arsenic and Certain Arsenic Compounds
- 1332-21-4 Asbestos
- 71-43-2 Benzene
- 92-87-5 Benzidine
- 542-88-1 Bis(chloromethyl)ether

  Also:
  107-30-2 technical grade Chloromethyl Methyl Ether
- 7440-47-3 Chromium and Certain Chromium Compounds

  Key hexavalent compounds are:

  10294-40-3 Barium Chromate
  13765-19-0 Calcium Chromate
  1333-82-0 Chromium Trioxide
  7758-97-6 Lead Chromate
  10588-01-9 Sodium Dichromate
  7789-06-2 Strontium Chromate
- 505-60-2 Bis(2-chloroethyl)sulfide (Mustard Gas)
- 91-59-8 2-Napthylamine
- 1314-20-1 Thorium Dioxide
- 75-01-4 Vinyl Chloride